

WHO PACKAGE LEAFLET

Package leaflet: Information for the user

Comirnaty JN.1 30 micrograms/dose dispersion for injection (frozen vials) Adults and adolescents from 12 years COVID-19 mRNA Vaccine bretovameran

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Comirnaty JN.1 is and what it is used for
2. What you need to know before you receive Comirnaty JN.1
3. How Comirnaty JN.1 is given
4. Possible side effects
5. How to store Comirnaty JN.1
6. Contents of the pack and other information

1. What Comirnaty JN.1 is and what it is used for

Comirnaty JN.1 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty JN.1 30 micrograms/dose dispersion for injection is given to adults and adolescents from 12 years of age and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty JN.1 does not contain the virus to produce immunity, it cannot give you COVID-19.

The use of this vaccine should be in accordance with official recommendations.

2. What you need to know before you receive Comirnaty JN.1

Comirnaty JN.1 should not be given

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given the vaccine if:

- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given this vaccine in the past.
- you are feeling nervous about the vaccination process or have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.

- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty JN.1 may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty JN.1 may be lower in people who are immunocompromised. If you are immunocompromised, you may receive additional doses of Comirnaty JN.1. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Children

Comirnaty JN.1 30 micrograms/dose dispersion for injection is not recommended for children aged under 12 years.

There are paediatric formulations available for infants aged 6 months and above and children below 12 years of age. For details, please refer to the WHO Package Leaflet for other formulations.

The vaccine is not recommended for infants aged under 6 months.

Other medicines and Comirnaty JN.1

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Comirnaty JN.1 may be given at the same time as a flu vaccine.

In adults 18 years of age and older, Comirnaty JN.1 may be given at the same time as a pneumococcal conjugated vaccine (PCV).

In adults 18 years of age and older, Comirnaty JN.1 may be given at the same time as a respiratory syncytial virus (RSV) vaccine.

In older adults 65 years of age and older, Comirnaty JN.1 may be given at the same time as a high dose flu and an RSV vaccine.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine.

No data are available yet regarding the use of Comirnaty JN.1 during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen. Comirnaty JN.1 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty JN.1 during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty JN.1 can be used while breast-feeding.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

3. How Comirnaty JN.1 is given

Comirnaty JN.1 is given as an injection of 0.3 mL into a muscle of your upper arm.

You will receive 1 injection, regardless whether you have received a COVID-19 vaccine before.

If you were previously vaccinated with a COVID-19 vaccine, you should not receive a dose of Comirnaty JN.1 until at least 3 months after the most recent dose.

If you are immunocompromised, you may receive additional doses of Comirnaty JN.1.

If you have any further questions on the use of Comirnaty JN.1, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty JN.1 can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people

- injection site: pain, swelling
- tiredness, headache
- muscle pain, joint pain
- chills, fever
- diarrhoea

Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.

Common side effects: may affect up to 1 in 10 people

- nausea
- vomiting ('very common' in pregnant women 18 years of age and older and in immunocompromised individuals 12 to 18 years of age)
- injection site redness ('very common' in immunocompromised individuals 12 years of age and older)
- enlarged lymph nodes (more frequently observed after a booster dose)

Uncommon side effects: may affect up to 1 in 100 people

- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- decreased appetite
- dizziness
- excessive sweating, night sweats

Rare side effects: may affect up to 1 in 1 000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10 000 people

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)

- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or “bulls-eye” with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Comirnaty JN.1

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

Single dose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of single dose vials of the vaccine can be thawed at 2 °C to 8 °C for 2 hours.

Multidose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 6 hours.

Thawed (previously frozen) vials: Once removed from the freezer, the unopened vial may be stored and transported refrigerated at 2 °C to 8 °C for up to 10 weeks; not exceeding the printed expiry date

(EXP). The outer carton should be marked with the new expiry date at 2 °C to 8 °C. Once thawed, the vaccine cannot be re-frozen.

Thawed vials can be handled in room light conditions.

Opened vials: Once the vaccine vial is punctured it should be used immediately or within 6 hours and kept at 2 °C to 8 °C. Discard any unused vaccine.

Do not use this vaccine if you notice particulates or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Comirnaty JN.1 contains

- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called bretovameran.
 - A single dose vial contains 1 dose of 0.3 mL with 30 micrograms bretovameran each.
 - A multidose vial contains 6 doses of 0.3 mL with 30 micrograms bretovameran each.
- The other ingredients are:
 - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
 - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
 - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
 - cholesterol
 - trometamol
 - trometamol hydrochloride
 - sucrose
 - water for injections

What Comirnaty JN.1 looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in either:

- A single dose vial of 1 dose in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal; or
- A multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal.

Single dose vials pack size: 10 vials

Multidose vials pack size: 10 vials

Not all pack sizes may be marketed.

Manufacturer

BioNTech Manufacturing GmbH

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This leaflet was last revised in {MM/YYYY}

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

The following information is intended for healthcare professionals only:

Administer Comirnaty JN.1 intramuscularly as a single dose of 0.3 mL regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty JN.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Additional doses may be given to individuals who are severely immunocompromised.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions prior to use for frozen vials

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Comirnaty JN.1 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has a **grey plastic cap** and the product **name is Comirnaty JN.1 30 micrograms/dose dispersion for injection** (12 years and older).
- If the vial has another product name on the label, please make reference to the WHO Product Information for that formulation.
- If the vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw. Ensure vials are completely thawed prior to use.
 - Single dose vials: A 10-vial pack of single dose vials may take 2 hours to thaw.
 - Multidose vials: A 10-vial pack of multidose vials may take 6 hours to thaw.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.
- Unopened vials can be **stored for up to 10 weeks at 2 °C to 8 °C**; not exceeding the printed expiry date (EXP).
- Thawed vials can be handled in room light conditions.

Preparation of 0.3 mL doses

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.

- Check whether the vial is a single dose vial or a multidose vial and follow the applicable handling instructions below:
 - Single dose vials
 - Withdraw a single 0.3 mL dose of vaccine.
 - Discard vial and any excess volume.
 - Multidose vials
 - Multidose vials contain 6 doses of 0.3 mL each.
 - Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
 - Withdraw 0.3 mL of Comirnaty JN.1.
 - **Low dead-volume syringes and/or needles** should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead-volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
 - Each dose must contain 0.3 mL of vaccine.
 - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
 - Record the appropriate date/time on the vial. Discard any unused vaccine 6 hours after first puncture.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Package leaflet: Information for the user

Comirnaty JN.1 30 micrograms/dose dispersion for injection (refrigerated only vials) Adults and adolescents from 12 years COVID-19 mRNA Vaccine bretovameran

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Comirnaty JN.1 is and what it is used for
2. What you need to know before you receive Comirnaty JN.1
3. How Comirnaty JN.1 is given
4. Possible side effects
5. How to store Comirnaty JN.1
6. Contents of the pack and other information

1. What Comirnaty JN.1 is and what it is used for

Comirnaty JN.1 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty JN.1 30 micrograms/dose dispersion for injection is given to adults and adolescents from 12 years of age and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty JN.1 does not contain the virus to produce immunity, it cannot give you COVID-19.

The use of this vaccine should be in accordance with official recommendations.

2. What you need to know before you receive Comirnaty JN.1

Comirnaty JN.1 should not be given

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given the vaccine if:

- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given this vaccine in the past.
- you are feeling nervous about the vaccination process or have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.

- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty JN.1 may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty JN.1 may be lower in people who are immunocompromised. If you are immunocompromised, you may receive additional doses of Comirnaty JN.1. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Children

Comirnaty JN.1 30 micrograms/dose dispersion for injection is not recommended for children aged under 12 years.

There are paediatric formulations available for infants aged 6 months and above and children below 12 years of age. For details, please refer to the WHO Package Leaflet for other formulations.

The vaccine is not recommended for infants aged under 6 months.

Other medicines and Comirnaty JN.1

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Comirnaty JN.1 may be given at the same time as a flu vaccine.

In adults 18 years of age and older, Comirnaty JN.1 may be given at the same time as a pneumococcal conjugated vaccine (PCV).

In adults 18 years of age and older, Comirnaty JN.1 may be given at the same time as a respiratory syncytial virus (RSV) vaccine.

In older adults 65 years of age and older, Comirnaty JN.1 may be given at the same time as a high dose flu and an RSV vaccine.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine.

No data are available yet regarding the use of Comirnaty JN.1 during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen. Comirnaty JN.1 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty JN.1 during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty JN.1 can be used while breast-feeding.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

3. How Comirnaty JN.1 is given

Comirnaty JN.1 is given as an injection of 0.3 mL into a muscle of your upper arm.

You will receive 1 injection, regardless whether you have received a COVID-19 vaccine before.

If you were previously vaccinated with a COVID-19 vaccine, you should not receive a dose of Comirnaty JN.1 until at least 3 months after the most recent dose.

If you are immunocompromised, you may receive additional doses of Comirnaty JN.1.

If you have any further questions on the use of Comirnaty JN.1, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty JN.1 can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people

- injection site: pain, swelling
- tiredness, headache
- muscle pain, joint pain
- chills, fever
- diarrhoea

Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.

Common side effects: may affect up to 1 in 10 people

- nausea
- vomiting ('very common' in pregnant women 18 years of age and older and in immunocompromised individuals 12 to 18 years of age)
- injection site redness ('very common' in immunocompromised individuals 12 years of age and older)
- enlarged lymph nodes (more frequently observed after a booster dose)

Uncommon side effects: may affect up to 1 in 100 people

- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- decreased appetite
- dizziness
- excessive sweating, night sweats

Rare side effects: may affect up to 1 in 1 000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10 000 people

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)

- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or “bulls-eye” with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Comirnaty JN.1

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP.

Store in a refrigerator at 2 °C to 8 °C. DO NOT FREEZE.

Store in the original package in order to protect from light.

The vials can be handled in room light conditions.

Opened vials: Once the vaccine vial is punctured it should be used immediately or within 6 hours and kept at 2 °C to 8 °C. Discard any unused vaccine.

Do not use this vaccine if you notice particulates or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Comirnaty JN.1 contains

- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called bretovameran. A multidose vial contains 6 doses of 0.3 mL with 30 micrograms bretovameran each.
- The other ingredients are:
 - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
 - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
 - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
 - cholesterol
 - trometamol
 - trometamol hydrochloride
 - sucrose
 - water for injections

What Comirnaty JN.1 looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in a multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal.

Multidose vials pack size: 10 vials

Manufacturer

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This leaflet was last revised in {MM/YYYY}

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

The following information is intended for healthcare professionals only:

Administer Comirnaty JN.1 intramuscularly as a single dose of 0.3 mL regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty JN.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Additional doses may be given to individuals who are severely immunocompromised.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions prior to use for refrigerated only vials

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Comirnaty JN.1 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has a **grey plastic cap** and the product **name is Comirnaty JN.1 30 micrograms/dose dispersion for injection** (12 years and older).
- If the vial has another product name on the label, please make reference to the WHO Product Information for that formulation.
- Unopened vials are **stored at 2 °C to 8 °C**; not exceeding the printed expiry date (EXP).
- The vials can be handled in room light conditions.

Preparation of 0.3 mL doses

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
- Multidose vials contain 6 doses of 0.3 mL each.
- Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty JN.1.
- **Low dead-volume syringes and/or needles** should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead-volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 6 hours after first puncture.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Package leaflet: Information for the user

Comirnaty JN.1 10 micrograms/dose dispersion for injection Infants and children 6 months to 11 years COVID-19 mRNA Vaccine bretovameran

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects your child may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before your child receives this vaccine because it contains important information for your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor, pharmacist or nurse.
- If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Comirnaty JN.1 is and what it is used for
2. What you need to know before your child receives Comirnaty JN.1
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6. Contents of the pack and other information

1. What Comirnaty JN.1 is and what it is used for

Comirnaty JN.1 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty JN.1 10 micrograms/dose dispersion for injection is given to infants and children from 6 months to 11 years of age.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty JN.1 does not contain the virus to produce immunity, it cannot give your child COVID-19.

The use of this vaccine should be in accordance with official recommendations.

2. What you need to know before your child receives Comirnaty JN.1

Comirnaty JN.1 should not be given

- if your child is allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your child's doctor, pharmacist or nurse before your child is given the vaccine if your child:

- has ever had a severe allergic reaction or breathing problems after any other vaccine injection or after having been given this vaccine in the past.
- is feeling nervous about the vaccination process or has ever fainted following any needle injection.

- has a severe illness or infection with high fever. However, your child can have the vaccination if he/she has a mild fever or upper airway infection like a cold.
- has a bleeding problem, bruises easily or uses a medicine to prevent blood-clots.
- has a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects the immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty JN.1 may not fully protect all those who receive it and it is not known how long your child will be protected.

The efficacy of Comirnaty JN.1 may be lower in people who are immunocompromised. If your child is immunocompromised, he/she may receive additional doses of Comirnaty JN.1. In these cases, your child should continue to maintain physical precautions to help prevent COVID-19. In addition, your child's close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your child's doctor.

Children

The vaccine is not recommended for infants aged under 6 months.

Other medicines and Comirnaty JN.1

Tell your child's doctor or pharmacist if your child is using, has recently used or might use any other medicines or has recently received any other vaccine.

Pregnancy and breast-feeding

If your child is pregnant, tell your child's doctor, nurse or pharmacist before your child receives this vaccine.

No data are available yet regarding the use of Comirnaty JN.1 during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen.

Comirnaty JN.1 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty JN.1 during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty JN.1 can be used while breast-feeding.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your child's ability to use machines or undertake activities such as cycling. Wait until these effects have worn off before resuming activities that require your child's full attention.

3. How Comirnaty JN.1 is given

Comirnaty JN.1 is given as an injection of 0.3 mL into a muscle of your child's upper arm.

Children 5 years to 11 years of age

Your child will receive 1 injection, regardless whether he/she has received a COVID-19 vaccine before.

If your child was previously vaccinated with a COVID-19 vaccine, he/she should not receive a dose of Comirnaty JN.1 until at least 3 months after the most recent dose.

Infants and children 6 months to 4 years of age

If your child has not received a COVID-19 vaccine in the past, your child will receive a maximum of 2 doses (the total number of doses required as a primary course). It is recommended to receive the second dose 8 weeks after the first dose to complete the primary course.

If your child turns 5 years old between their doses in the primary course, he/she should complete the primary course at the same 10 micrograms dose level.

If your child has previously completed a COVID-19 primary vaccination course, your child will receive 1 injection. If your child was previously vaccinated with a COVID-19 vaccine, your child should not receive a dose of Comirnaty JN.1 until at least 3 months after the most recent dose.

If your child has previously received 1 or 2 doses of the 3 micrograms 3-dose primary course but has not completed the COVID-19 primary vaccination course, he/she may receive additional doses of Comirnaty JN.1 10 micrograms. The second dose may be administered 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose.

Immunocompromised infants and children 6 months to 11 years of age

If your child is immunocompromised, he/she may receive additional doses of Comirnaty JN.1.

If you have any further questions on the use of Comirnaty JN.1, ask your child's doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty JN.1 can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people

- irritability (6 months to less than 2 years)
- injection site: pain/tenderness, swelling
- tiredness, headache
- drowsiness (6 months to less than 2 years)
- muscle pain, joint pain
- chills, fever
- diarrhoea

Common side effects: may affect up to 1 in 10 people

- nausea
- vomiting ('very common' in pregnant women 18 years of age and older and in immunocompromised individuals 2 to 18 years of age)
- injection site redness ('very common' in 6 months to 11 years of age and in immunocompromised individuals 2 years of age and older)
- enlarged lymph nodes (more frequently observed after a booster dose)

Uncommon side effects: may affect up to 1 in 100 people

- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash ('common' for 6 months to less than 2 years) or itching
- decreased appetite ('very common' for 6 months to less than 2 years)
- dizziness
- excessive sweating, night sweats

Rare side effects: may affect up to 1 in 1 000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10 000 people

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)

- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects

If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Comirnaty JN.1

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

Single dose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of single dose vials of the vaccine can be thawed at 2 °C to 8 °C for 2 hours.

Multidose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of single dose vials of the vaccine can be thawed at 2 °C to 8 °C for 6 hours.

Thawed (previously frozen) vials: Once removed from the freezer, the unopened vial may be stored and transported refrigerated at 2 °C to 8 °C for up to 10 weeks; not exceeding the printed expiry date (EXP). The outer carton should be marked with the new expiry date at 2 °C to 8 °C. Once thawed, the vaccine cannot be re-frozen.

Thawed vials can be handled in room light conditions.

Opened vials: After the vaccine vial is first punctured it should be used immediately or within 6 hours and kept at 2 °C to 8 °C. Discard any unused vaccine.

Do not use this vaccine if you notice particulates or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Comirnaty JN.1 contains

- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called bretovameran.
 - A single dose vial contains 1 dose of 0.3 mL with 10 micrograms of bretovameran per dose.
 - A multidose vial contains 6 doses of 0.3 mL with 10 micrograms of bretovameran per dose.
- The other ingredients are:
 - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
 - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
 - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
 - cholesterol
 - trometamol
 - trometamol hydrochloride
 - sucrose
 - water for injections

What Comirnaty JN.1 looks like and contents of the pack

The vaccine is a clear to slightly opalescent dispersion (pH: 6.9 - 7.9) provided in either:

- A single dose vial of 1 dose in a 2 mL clear vial (type I glass), with a rubber stopper and a blue flip-off plastic cap with aluminium seal; or
- A multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a blue flip-off plastic cap with aluminium seal.

Single dose vials pack size: 10 vials

Multidose vials pack size: 10 vials

Not all pack sizes may be marketed.

Manufacturer

BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz
Germany
Phone: +49 6131 9084-0
Fax: +49 6131 9084-2121
service@biontech.de

This leaflet was last revised in {MM/YYYY}

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

The following information is intended for healthcare professionals only:

Children 5 years to 11 years of age

Administer Comirnaty JN.1 intramuscularly as a single dose of 0.3 mL regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty JN.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Infants and children 6 months to 4 years of age

If the child has not received a COVID-19 vaccine, administer Comirnaty JN.1 intramuscularly as a primary course of 2 doses of 0.3 mL. Administer the second dose 8 weeks after the first dose.

If the child has completed a COVID-19 vaccine primary course, administer Comirnaty JN.1 intramuscularly as a single dose of 0.3 mL. For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty JN.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

If the child has received 1 or 2 doses of the 3 micrograms 3-dose primary series but has not completed the primary vaccination course, additional doses of Comirnaty JN.1 10 micrograms may be given. The second dose may be administered 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose.

Immunocompromised infants and children 6 months to 11 years of age

Additional doses may be given to individuals who are severely immunocompromised.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions prior to use

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Comirnaty JN.1 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has a **blue plastic cap** and the product **name is Comirnaty JN.1 10 micrograms/dose dispersion for injection** (infants and children 6 months to 11 years).
- If the vial has another product name on the label, please make reference to the WHO Product Information for that formulation.
- If the vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw. Ensure vials are completely thawed prior to use.
 - Single dose vials: A 10-vial pack of single dose vials may take 2 hours to thaw.
 - Multidose vials: A 10-vial pack of multidose vials may take 6 hours to thaw.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.
- Unopened vials can be **stored for up to 10 weeks at 2 °C to 8 °C**; not exceeding the printed expiry date (EXP).
- Thawed vials can be handled in room light conditions.

Preparation of 0.3 mL doses

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
- Check whether the vial is a single dose vial or a multidose vial and follow the applicable handling instructions below:
 - Single dose vials
 - Withdraw a single 0.3 mL dose of vaccine.
 - Discard vial and any excess volume.
 - Multidose vials
 - Multidose vials contain 6 doses of 0.3 mL each.
 - Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
 - Withdraw 0.3 mL of Comirnaty JN.1 for infants and children aged 6 months to 11 years.
 - **Low dead-volume syringes and/or needles** should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead-volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
 - Each dose must contain 0.3 mL of vaccine.
 - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
 - Record the appropriate date/time on the vial. Discard any unused vaccine 6 hours after first puncture.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Package leaflet: Information for the user

Comirnaty JN.1 10 micrograms/dose concentrate for dispersion for injection Infants and children 6 months to 11 year COVID-19 mRNA Vaccine bretovameran

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects your child may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before your child receives this vaccine because it contains important information for your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor, pharmacist or nurse.
- If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Comirnaty JN.1 is and what it is used for
2. What you need to know before your child receives Comirnaty JN.1
3. How Comirnaty JN.1 is given
4. Possible side effects
5. How to store Comirnaty JN.1
6. Contents of the pack and other information

1. What Comirnaty JN.1 is and what it is used for

Comirnaty JN.1 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty JN.1 10 micrograms/dose concentrate for dispersion for injection is given to infants and children from 6 months to 11 years of age.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty JN.1 does not contain the virus to produce immunity, it cannot give your child COVID-19.

The use of this vaccine should be in accordance with official recommendations.

2. What you need to know before your child receives Comirnaty JN.1

Comirnaty JN.1 should not be given

- if your child is allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your child's doctor, pharmacist or nurse before your child is given the vaccine if your child:

- has ever had a severe allergic reaction or breathing problems after any other vaccine injection or after having been given this vaccine in the past.
- is feeling nervous about the vaccination process or has ever fainted following any needle injection.

- has a severe illness or infection with high fever. However, your child can have the vaccination if he/she has a mild fever or upper airway infection like a cold.
- has a bleeding problem, bruises easily or uses a medicine to prevent blood-clots.
- has a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects the immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty JN.1 may not fully protect all those who receive it and it is not known how long your child will be protected.

The efficacy of Comirnaty JN.1 may be lower in people who are immunocompromised. If your child is immunocompromised, he/she may receive additional doses of Comirnaty JN.1. In these cases, your child should continue to maintain physical precautions to help prevent COVID-19. In addition, your child's close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your child's doctor.

Children

The vaccine is not recommended for infants aged under 6 months.

Other medicines and Comirnaty JN.1

Tell your child's doctor or pharmacist if your child is using, has recently used or might use any other medicines or has recently received any other vaccine.

Pregnancy and breast-feeding

If your child is pregnant, tell your child's doctor, nurse or pharmacist before your child receives this vaccine.

No data are available yet regarding the use of Comirnaty JN.1 during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen.

Comirnaty JN.1 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty JN.1 during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty JN.1 can be used while breast-feeding.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your child's ability to use machines or undertake activities such as cycling. Wait until these effects have worn off before resuming activities that require your child's full attention.

3. How Comirnaty JN.1 is given

Comirnaty JN.1 is given after dilution as an injection of 0.2 mL into a muscle of your child's upper arm.

Children 5 years to 11 years of age

Your child will receive 1 injection, regardless whether he/she has received a COVID-19 vaccine before.

If your child was previously vaccinated with a COVID-19 vaccine, he/she should not receive a dose of Comirnaty JN.1 until at least 3 months after the most recent dose.

Infants and children 6 months to 4 years of age

If your child has not received a COVID-19 vaccine in the past, your child will receive a maximum of 2 doses (the total number of doses required as a primary course). It is recommended to receive the second dose 8 weeks after the first dose to complete the primary course.

If your child turns 5 years old between their doses in the primary course, he/she should complete the primary course at the same 10 micrograms dose level.

If your child has previously completed a COVID-19 primary vaccination course, your child will receive 1 injection. If your child was previously vaccinated with a COVID-19 vaccine, your child should not receive a dose of Comirnaty JN.1 until at least 3 months after the most recent dose.

If your child has previously received 1 or 2 doses of the 3 micrograms 3-dose primary course but has not completed the COVID-19 primary vaccination course, he/she may receive additional doses of Comirnaty JN.1 10 micrograms. The second dose may be administered 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose.

Immunocompromised infants and children 6 months to 11 years of age

If your child is immunocompromised, he/she may receive additional doses of Comirnaty JN.1.

If you have any further questions on the use of Comirnaty JN.1, ask your child's doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty JN.1 can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people

- irritability (6 months to less than 2 years)
- injection site: pain/tenderness, swelling
- tiredness, headache
- drowsiness (6 months to less than 2 years)
- muscle pain, joint pain
- chills, fever
- diarrhoea

Common side effects: may affect up to 1 in 10 people

- nausea
- vomiting ('very common' in pregnant women 18 years of age and older and in immunocompromised individuals 2 to 18 years of age)
- injection site redness ('very common' in 6 months to 11 years of age and in immunocompromised individuals 2 years of age and older)

- enlarged lymph nodes (more frequently observed after a booster dose)

Uncommon side effects: may affect up to 1 in 100 people

- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash ('common' for 6 months to less than 2 years) or itching
- decreased appetite ('very common' for 6 months to less than 2 years)
- dizziness
- excessive sweating, night sweats

Rare side effects: may affect up to 1 in 1 000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10 000 people

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)

- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects

If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Comirnaty JN.1

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 4 hours.

Thawed (previously frozen) vials: Once removed from the freezer, the unopened vial may be stored and transported refrigerated at 2 °C to 8 °C for up to 10 weeks; not exceeding the printed expiry date (EXP). The outer carton should be marked with the new expiry date at 2 °C to 8 °C. Once thawed, the vaccine cannot be re-frozen.

Thawed vials can be handled in room light conditions.

Once the vaccine vial is diluted, it should be used immediately or within 6 hours and kept at 2 °C to 8 °C. Discard any unused vaccine.

Do not use this vaccine if you notice particulates in the dilution or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Comirnaty JN.1 contains

- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called bretovameran. After dilution, the vial contains 10 doses of 0.2 mL with 10 micrograms bretovameran each.
- The other ingredients are:
 - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
 - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
 - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
 - cholesterol
 - trometamol
 - trometamol hydrochloride
 - sucrose
 - water for injections

What Comirnaty JN.1 looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in a multidose vial of 10 doses in a 2 mL clear vial (type I glass), with a rubber stopper and an orange flip-off plastic cap with aluminium seal.

Pack size: 10 vials

Manufacturer

BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz
Germany
Phone: +49 6131 9084-0
Fax: +49 6131 9084-2121
service@biontech.de

This leaflet was last revised in {MM/YYYY}

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

The following information is intended for healthcare professionals only:

Children 5 years to 11 years of age

Administer Comirnaty JN.1 intramuscularly after dilution as a single dose of 0.2 mL regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty JN.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Infants and children 6 months to 4 years of age

If the child has not received a COVID-19 vaccine, administer Comirnaty JN.1 intramuscularly as a primary course of 2 doses of 0.2 mL. Administer the second dose 8 weeks after the first dose.

If the child has completed a COVID-19 vaccine primary course, administer Comirnaty JN.1 intramuscularly as a single dose of 0.2 mL. For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty JN.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

If the child has received 1 or 2 doses of the 3 micrograms 3-dose primary series but has not completed the primary vaccination course, additional doses of Comirnaty JN.1 10 micrograms may be given. The second dose may be administered 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose.

Immunocompromised infants and children 6 months to 11 years of age

Additional doses may be given to individuals who are severely immunocompromised.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions prior to use

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Comirnaty JN.1 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has an **orange plastic cap** and the product **name is Comirnaty JN.1 10 micrograms/dose concentrate for dispersion for injection** (infants and children 6 months to 11 years).
- If the vial has another product name on the label, please make reference to the WHO Product Information for that formulation.

- If the vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10-vial pack may take 4 hours to thaw. Ensure vials are completely thawed prior to use.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.
- Unopened vials can be **stored for up to 10 weeks at 2 °C to 8 °C**; not exceeding the printed expiry date (EXP).
- Thawed vials can be handled in room light conditions.

Dilution

- Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
- Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.
- The thawed vaccine must be diluted in its original vial with **1.3 mL sodium chloride 9 mg/mL (0.9%) solution for injection**, using a 21 gauge or narrower needle and aseptic techniques.
- Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.3 mL air into the empty diluent syringe.
- Gently invert the diluted dispersion 10 times. Do not shake.
- The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
- The diluted vials should be marked with the appropriate **discard date and time**.
- **After dilution**, store at 2 °C to 8 °C and use within **6 hours**.
- Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

Preparation of 0.2 ml doses

- After dilution, the vial contains 2.6 mL from which 10 doses of 0.2 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
- Withdraw 0.2 mL of Comirnaty JN.1 for infants and children aged 6 months to 11 years.
- **Low dead-volume syringes and/or needles** should be used in order to extract 10 doses from a single vial. The low dead-volume syringe and needle combination should have a dead-volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract ten doses from a single vial.
- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
- Discard any unused vaccine within 6 hours after dilution.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Package leaflet: Information for the user

Comirnaty LP.8.1 30 micrograms/dose dispersion for injection (frozen vials) Adults and adolescents from 12 years COVID-19 mRNA Vaccine mRNA encoding LP.8.1

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Comirnaty LP.8.1 is and what it is used for
2. What you need to know before you receive Comirnaty LP.8.1
3. How Comirnaty LP.8.1 is given
4. Possible side effects
5. How to store Comirnaty LP.8.1
6. Contents of the pack and other information

1. What Comirnaty LP.8.1 is and what it is used for

Comirnaty LP.8.1 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty LP.8.1 30 micrograms/dose dispersion for injection is given to adults and adolescents from 12 years of age and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty LP.8.1 does not contain the virus to produce immunity, it cannot give you COVID-19.

The use of this vaccine should be in accordance with official recommendations.

2. What you need to know before you receive Comirnaty LP.8.1

Comirnaty LP.8.1 should not be given

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given the vaccine if:

- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given this vaccine in the past.
- you are feeling nervous about the vaccination process or have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.

- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty LP.8.1 may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty LP.8.1 may be lower in people who are immunocompromised. If you are immunocompromised, you may receive additional doses of Comirnaty LP.8.1. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Children

Comirnaty LP.8.1 30 micrograms/dose dispersion for injection is not recommended for children aged under 12 years.

There are paediatric formulations available for infants aged 6 months and above and children below 12 years of age. For details, please refer to the WHO Package Leaflet for other formulations.

The vaccine is not recommended for infants aged under 6 months.

Other medicines and Comirnaty LP.8.1

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Comirnaty LP.8.1 may be given at the same time as a flu vaccine.

In adults 18 years of age and older, Comirnaty LP.8.1 may be given at the same time as a pneumococcal conjugated vaccine (PCV).

In adults 18 years of age and older, Comirnaty LP.8.1 may be given at the same time as a respiratory syncytial virus (RSV) vaccine.

In older adults 65 years of age and older, Comirnaty LP.8.1 may be given at the same time as a high dose flu and an RSV vaccine.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine.

No data are available yet regarding the use of Comirnaty LP.8.1 during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen. Comirnaty LP.8.1 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty LP.8.1 during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty LP.8.1 can be used while breast-feeding.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

3. How Comirnaty LP.8.1 is given

Comirnaty LP.8.1 is given as an injection of 0.3 mL into a muscle of your upper arm.

You will receive 1 injection, regardless whether you have received a COVID-19 vaccine before.

If you were previously vaccinated with a COVID-19 vaccine, you should not receive a dose of Comirnaty LP.8.1 until at least 3 months after the most recent dose.

If you are immunocompromised, you may receive additional doses of Comirnaty LP.8.1.

If you have any further questions on the use of Comirnaty LP.8.1, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty LP.8.1 can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people

- injection site: pain, swelling
- tiredness, headache
- muscle pain, joint pain
- chills, fever
- diarrhoea

Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.

Common side effects: may affect up to 1 in 10 people

- nausea
- vomiting ('very common' in pregnant women 18 years of age and older and in immunocompromised individuals 12 to 18 years of age)
- injection site redness ('very common' in immunocompromised individuals 12 years of age and older)
- enlarged lymph nodes (more frequently observed after a booster dose)

Uncommon side effects: may affect up to 1 in 100 people

- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- decreased appetite
- dizziness

- excessive sweating, night sweats

Rare side effects: may affect up to 1 in 1 000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10 000 people

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)

- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or “bulls-eye” with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Comirnaty LP.8.1

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 6 hours.

Thawed (previously frozen) vials: Once removed from the freezer, the unopened vial may be stored and transported refrigerated at 2 °C to 8 °C for up to 10 weeks; not exceeding the printed expiry date (EXP). The outer carton should be marked with the new expiry date at 2 °C to 8 °C. Once thawed, the vaccine cannot be re-frozen.

Thawed vials can be handled in room light conditions.

Opened vials: Once the vaccine vial is punctured it should be used immediately or within 6 hours and kept at 2 °C to 8 °C. Discard any unused vaccine.

Do not use this vaccine if you notice particulates or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Comirnaty LP.8.1 contains

- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called mRNA encoding LP.8.1.
 - A multidose vial contains 6 doses of 0.3 mL with 30 micrograms mRNA encoding LP.8.1 each.
- The other ingredients are:
 - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
 - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
 - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
 - cholesterol
 - trometamol
 - trometamol hydrochloride
 - sucrose
 - water for injections

What Comirnaty LP.8.1 looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in a multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal.

Multidose vials pack size: 10 vials

Manufacturer

BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz
Germany
Phone: +49 6131 9084-0
Fax: +49 6131 9084-2121
service@biontech.de

This leaflet was last revised in {MM/YYYY}

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

The following information is intended for healthcare professionals only:

Administer Comirnaty LP.8.1 intramuscularly as a single dose of 0.3 mL regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty LP.8.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Additional doses may be given to individuals who are severely immunocompromised.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions prior to use for frozen vials

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Comirnaty LP.8.1 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has a **grey plastic cap** and the product **name is Comirnaty LP.8.1 30 micrograms/dose dispersion for injection** (12 years and older).
- If the vial has another product name on the label, please make reference to the WHO Product Information for that formulation.
- If the vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw. Ensure vials are completely thawed prior to use. A 10-vial pack of multidose vials may take 6 hours to thaw.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.
- Unopened vials can be **stored for up to 10 weeks at 2 °C to 8 °C**; not exceeding the printed expiry date (EXP).
- Thawed vials can be handled in room light conditions.

Preparation of 0.3 mL doses

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
 - Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
 - Withdraw 0.3 mL of Comirnaty LP.8.1.
 - **Low dead-volume syringes and/or needles** should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead-volume of no more than 35 microlitres. If standard syringes and

needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 6 hours after first puncture.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Package leaflet: Information for the user

Comirnaty LP.8.1 30 micrograms/dose dispersion for injection (refrigerated only vials) Adults and adolescents from 12 years COVID-19 mRNA Vaccine mRNA encoding LP.8.1

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Comirnaty LP.8.1 is and what it is used for
2. What you need to know before you receive Comirnaty LP.8.1
3. How Comirnaty LP.8.1 is given
4. Possible side effects
5. How to store Comirnaty LP.8.1
6. Contents of the pack and other information

1. What Comirnaty LP.8.1 is and what it is used for

Comirnaty LP.8.1 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty LP.8.1 30 micrograms/dose dispersion for injection is given to adults and adolescents from 12 years of age and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty LP.8.1 does not contain the virus to produce immunity, it cannot give you COVID-19.

The use of this vaccine should be in accordance with official recommendations.

2. What you need to know before you receive Comirnaty LP.8.1

Comirnaty LP.8.1 should not be given

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given the vaccine if:

- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given this vaccine in the past.
- you are feeling nervous about the vaccination process or have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.

- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty LP.8.1 may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty LP.8.1 may be lower in people who are immunocompromised. If you are immunocompromised, you may receive additional doses of Comirnaty LP.8.1. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Children

Comirnaty LP.8.1 30 micrograms/dose dispersion for injection is not recommended for children aged under 12 years.

There are paediatric formulations available for infants aged 6 months and above and children below 12 years of age. For details, please refer to the WHO Package Leaflet for other formulations.

The vaccine is not recommended for infants aged under 6 months.

Other medicines and Comirnaty LP.8.1

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Comirnaty LP.8.1 may be given at the same time as a flu vaccine.

In adults 18 years of age and older, Comirnaty LP.8.1 may be given at the same time as a pneumococcal conjugated vaccine (PCV).

In adults 18 years of age and older, Comirnaty LP.8.1 may be given at the same time as a respiratory syncytial virus (RSV) vaccine.

In older adults 65 years of age and older, Comirnaty LP.8.1 may be given at the same time as a high dose flu and an RSV vaccine.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine.

No data are available yet regarding the use of Comirnaty LP.8.1 during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen. Comirnaty LP.8.1 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty LP.8.1 during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty LP.8.1 can be used while breast-feeding.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

3. How Comirnaty LP.8.1 is given

Comirnaty LP.8.1 is given as an injection of 0.3 mL into a muscle of your upper arm.

You will receive 1 injection, regardless whether you have received a COVID-19 vaccine before.

If you were previously vaccinated with a COVID-19 vaccine, you should not receive a dose of Comirnaty LP.8.1 until at least 3 months after the most recent dose.

If you are immunocompromised, you may receive additional doses of Comirnaty LP.8.1.

If you have any further questions on the use of Comirnaty LP.8.1, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty LP.8.1 can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people

- injection site: pain, swelling
- tiredness, headache
- muscle pain, joint pain
- chills, fever
- diarrhoea

Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.

Common side effects: may affect up to 1 in 10 people

- nausea
- vomiting ('very common' in pregnant women 18 years of age and older and in immunocompromised individuals 12 to 18 years of age)
- injection site redness ('very common' in immunocompromised individuals 12 years of age and older)
- enlarged lymph nodes (more frequently observed after a booster dose)

Uncommon side effects: may affect up to 1 in 100 people

- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- decreased appetite
- dizziness

- excessive sweating, night sweats

Rare side effects: may affect up to 1 in 1 000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10 000 people

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)

- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or “bulls-eye” with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Comirnaty LP.8.1

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP.

Store in a refrigerator at 2 °C to 8 °C. DO NOT FREEZE.

Store in the original package in order to protect from light.

The vials can be handled in room light conditions.

Opened vials: Once the vaccine vial is punctured it should be used immediately or within 6 hours and kept at 2 °C to 8 °C. Discard any unused vaccine.

Do not use this vaccine if you notice particulates or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Comirnaty LP.8.1 contains

- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called mRNA encoding LP.8.1. A multidose vial contains 6 doses of 0.3 mL with 30 micrograms mRNA encoding LP.8.1 each.
- The other ingredients are:
 - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
 - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
 - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
 - cholesterol
 - trometamol
 - trometamol hydrochloride
 - sucrose
 - water for injections

What Comirnaty LP.8.1 looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in a multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal.

Multidose vials pack size: 10 vials

Manufacturer

BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz
Germany
Phone: +49 6131 9084-0
Fax: +49 6131 9084-2121
service@biontech.de

This leaflet was last revised in {MM/YYYY}

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

The following information is intended for healthcare professionals only:

Administer Comirnaty LP.8.1 intramuscularly as a single dose of 0.3 mL regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty LP.8.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Additional doses may be given to individuals who are severely immunocompromised.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions prior to use for refrigerated only vials

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Comirnaty LP.8.1 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has a **grey plastic cap** and the product **name is Comirnaty LP.8.1 30 micrograms/dose dispersion for injection** (12 years and older).
- If the vial has another product name on the label, please make reference to the WHO Product Information for that formulation.
- Unopened vials are **stored at 2 °C to 8 °C**; not exceeding the printed expiry date (EXP).
- The vials can be handled in room light conditions.

Preparation of 0.3 mL doses

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
- Multidose vials contain 6 doses of 0.3 mL each.
- Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty LP.8.1.
- **Low dead-volume syringes and/or needles** should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead-volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 6 hours after first puncture.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Package leaflet: Information for the user

Comirnaty LP.8.1 10 micrograms/dose dispersion for injection Infants and children 6 months to 11 years COVID-19 mRNA Vaccine mRNA encoding LP.8.1

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects your child may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before your child receives this vaccine because it contains important information for your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor, pharmacist or nurse.
- If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Comirnaty LP.8.1 is and what it is used for
2. What you need to know before your child receives Comirnaty LP.8.1
3. How Comirnaty LP.8.1 is given
4. Possible side effects
5. How to store Comirnaty LP.8.1
6. Contents of the pack and other information

1. What Comirnaty LP.8.1 is and what it is used for

Comirnaty LP.8.1 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty LP.8.1 10 micrograms/dose dispersion for injection is given to infants and children from 6 months to 11 years of age.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty LP.8.1 does not contain the virus to produce immunity, it cannot give your child COVID-19.

The use of this vaccine should be in accordance with official recommendations.

2. What you need to know before your child receives Comirnaty LP.8.1

Comirnaty LP.8.1 should not be given

- if your child is allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your child's doctor, pharmacist or nurse before your child is given the vaccine if your child:

- has ever had a severe allergic reaction or breathing problems after any other vaccine injection or after having been given this vaccine in the past.
- is feeling nervous about the vaccination process or has ever fainted following any needle injection.

- has a severe illness or infection with high fever. However, your child can have the vaccination if he/she has a mild fever or upper airway infection like a cold.
- has a bleeding problem, bruises easily or uses a medicine to prevent blood-clots.
- has a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects the immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty LP.8.1 may not fully protect all those who receive it and it is not known how long your child will be protected.

The efficacy of Comirnaty LP.8.1 may be lower in people who are immunocompromised. If your child is immunocompromised, he/she may receive additional doses of Comirnaty LP.8.1. In these cases, your child should continue to maintain physical precautions to help prevent COVID-19. In addition, your child's close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your child's doctor.

Children

The vaccine is not recommended for infants aged under 6 months.

Other medicines and Comirnaty LP.8.1

Tell your child's doctor or pharmacist if your child is using, has recently used or might use any other medicines or has recently received any other vaccine.

Pregnancy and breast-feeding

If your child is pregnant, tell your child's doctor, nurse or pharmacist before your child receives this vaccine.

No data are available yet regarding the use of Comirnaty LP.8.1 during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen.

Comirnaty LP.8.1 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty LP.8.1 during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty LP.8.1 can be used while breast-feeding.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your child's ability to use machines or undertake activities such as cycling. Wait until these effects have worn off before resuming activities that require your child's full attention.

3. How Comirnaty LP.8.1 is given

Comirnaty LP.8.1 is given as an injection of 0.3 mL into a muscle of your child's upper arm.

Children 5 years to 11 years of age

Your child will receive 1 injection, regardless whether he/she has received a COVID-19 vaccine before.

If your child was previously vaccinated with a COVID-19 vaccine, he/she should not receive a dose of Comirnaty LP.8.1 until at least 3 months after the most recent dose.

Infants and children 6 months to 4 years of age

If your child has not received a COVID-19 vaccine in the past, your child will receive a maximum of 2 doses (the total number of doses required as a primary course). It is recommended to receive the second dose 8 weeks after the first dose to complete the primary course.

If your child turns 5 years old between their doses in the primary course, he/she should complete the primary course at the same 10 micrograms dose level.

If your child has previously completed a COVID-19 primary vaccination course, your child will receive 1 injection. If your child was previously vaccinated with a COVID-19 vaccine, your child should not receive a dose of Comirnaty LP.8.1 until at least 3 months after the most recent dose.

If your child has previously received 1 or 2 doses of the 3 micrograms 3-dose primary course but has not completed the COVID-19 primary vaccination course, he/she may receive additional doses of Comirnaty LP.8.1 10 micrograms. The second dose may be administered 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose.

Immunocompromised infants and children 6 months to 11 years of age

If your child is immunocompromised, he/she may receive additional doses of Comirnaty LP.8.1.

If you have any further questions on the use of Comirnaty LP.8.1, ask your child's doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty LP.8.1 can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people

- irritability (6 months to less than 2 years)
- injection site: pain/tenderness, swelling
- tiredness, headache
- drowsiness (6 months to less than 2 years)
- muscle pain, joint pain
- chills, fever
- diarrhoea

Common side effects: may affect up to 1 in 10 people

- nausea
- vomiting ('very common' in pregnant women 18 years of age and older and in immunocompromised individuals 2 to 18 years of age)
- injection site redness ('very common' in 6 months to 11 years of age and in immunocompromised individuals 2 years of age and older)
- enlarged lymph nodes (more frequently observed after a booster dose)

Uncommon side effects: may affect up to 1 in 100 people

- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia

- injection site itching
- allergic reactions such as rash ('common' for 6 months to less than 2 years) or itching
- decreased appetite ('very common' for 6 months to less than 2 years)
- dizziness
- excessive sweating, night sweats

Rare side effects: may affect up to 1 in 1 000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10 000 people

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)

- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects

If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Comirnaty LP.8.1

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

Single dose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of single dose vials of the vaccine can be thawed at 2 °C to 8 °C for 2 hours.

Multidose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of single dose vials of the vaccine can be thawed at 2 °C to 8 °C for 6 hours.

Thawed (previously frozen) vials: Once removed from the freezer, the unopened vial may be stored and transported refrigerated at 2 °C to 8 °C for up to 10 weeks; not exceeding the printed expiry date (EXP). The outer carton should be marked with the new expiry date at 2 °C to 8 °C. Once thawed, the vaccine cannot be re-frozen.

Thawed vials can be handled in room light conditions.

Opened vials: After the vaccine vial is first punctured it should be used immediately or within 6 hours and kept at 2 °C to 8 °C. Discard any unused vaccine.

Do not use this vaccine if you notice particulates or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Comirnaty LP.8.1 contains

- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called mRNA encoding LP.8.1.
 - A single dose vial contains 1 dose of 0.3 mL with 10 micrograms of mRNA encoding LP.8.1 per dose.
 - A multidose vial contains 6 doses of 0.3 mL with 10 micrograms of mRNA encoding LP.8.1 per dose.
- The other ingredients are:
 - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
 - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
 - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
 - cholesterol
 - trometamol
 - trometamol hydrochloride
 - sucrose
 - water for injections

What Comirnaty LP.8.1 looks like and contents of the pack

The vaccine is a clear to slightly opalescent dispersion (pH: 6.9 - 7.9) provided in either:

- A single dose vial of 1 dose in a 2 mL clear vial (type I glass), with a rubber stopper and a blue flip-off plastic cap with aluminium seal; or
- A multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a blue flip-off plastic cap with aluminium seal.

Single dose vials pack size: 10 vials

Multidose vials pack size: 10 vials

Not all pack sizes may be marketed.

Manufacturer

BioNTech Manufacturing GmbH
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55131 Mainz
Germany
Phone: +49 6131 9084-0
Fax: +49 6131 9084-2121
service@biontech.de

This leaflet was last revised in {MM/YYYY}

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

The following information is intended for healthcare professionals only:

Children 5 years to 11 years of age

Administer Comirnaty LP.8.1 intramuscularly as a single dose of 0.3 mL regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty LP.8.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Infants and children 6 months to 4 years of age

If the child has not received a COVID-19 vaccine, administer Comirnaty LP.8.1 intramuscularly as a primary course of 2 doses of 0.3 mL. Administer the second dose 8 weeks after the first dose.

If the child has completed a COVID-19 vaccine primary course, administer Comirnaty LP.8.1 intramuscularly as a single dose of 0.3 mL. For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty LP.8.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

If the child has received 1 or 2 doses of the 3 micrograms 3-dose primary series but has not completed the primary vaccination course, additional doses of Comirnaty LP.8.1 10 micrograms may be given. The second dose may be administered 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose.

Immunocompromised infants and children 6 months to 11 years of age

Additional doses may be given to individuals who are severely immunocompromised.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions prior to use

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Comirnaty LP.8.1 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has a **blue plastic cap** and the product **name is Comirnaty LP.8.1 10 micrograms/dose dispersion for injection** (infants and children 6 months to 11 years).
- If the vial has another product name on the label, please make reference to the WHO Product Information for that formulation.
- If the vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw. Ensure vials are completely thawed prior to use.
 - Single dose vials: A 10-vial pack of single dose vials may take 2 hours to thaw.
 - Multidose vials: A 10-vial pack of multidose vials may take 6 hours to thaw.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.
- Unopened vials can be **stored for up to 10 weeks at 2 °C to 8 °C**; not exceeding the printed expiry date (EXP).
- Thawed vials can be handled in room light conditions.

Preparation of 0.3 mL doses

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
- Check whether the vial is a single dose vial or a multidose vial and follow the applicable handling instructions below:
 - Single dose vials
 - Withdraw a single 0.3 mL dose of vaccine.
 - Discard vial and any excess volume.
 - Multidose vials
 - Multidose vials contain 6 doses of 0.3 mL each.
 - Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
 - Withdraw 0.3 mL of Comirnaty LP.8.1 for infants and children aged 6 months to 11 years.
 - **Low dead-volume syringes and/or needles** should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead-volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
 - Each dose must contain 0.3 mL of vaccine.
 - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
 - Record the appropriate date/time on the vial. Discard any unused vaccine 6 hours after first puncture.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Package leaflet: Information for the user

Comirnaty XFG 30 micrograms/dose dispersion for injection (frozen vials) Adults and adolescents from 12 years COVID-19 mRNA Vaccine mRNA encoding XFG

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Comirnaty XFG is and what it is used for
2. What you need to know before you receive Comirnaty XFG
3. How Comirnaty XFG is given
4. Possible side effects
5. How to store Comirnaty XFG
6. Contents of the pack and other information

1. What Comirnaty XFG is and what it is used for

Comirnaty XFG is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty XFG 30 micrograms/dose dispersion for injection is given to adults and adolescents from 12 years of age and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty XFG does not contain the virus to produce immunity, it cannot give you COVID-19.

The use of this vaccine should be in accordance with official recommendations.

2. What you need to know before you receive Comirnaty XFG

Comirnaty XFG should not be given

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given the vaccine if:

- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given this vaccine in the past.
- you are feeling nervous about the vaccination process or have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.

- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty XFG may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty XFG may be lower in people who are immunocompromised. If you are immunocompromised, you may receive additional doses of Comirnaty XFG. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Children

Comirnaty XFG 30 micrograms/dose dispersion for injection is not recommended for children aged under 12 years.

There are paediatric formulations available for infants aged 6 months and above and children below 12 years of age. For details, please refer to the WHO Package Leaflet for other formulations.

The vaccine is not recommended for infants aged under 6 months.

Other medicines and Comirnaty XFG

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Comirnaty XFG may be given at the same time as a flu vaccine.

In adults 18 years of age and older, Comirnaty XFG may be given at the same time as a pneumococcal conjugated vaccine (PCV).

In adults 18 years of age and older, Comirnaty XFG may be given at the same time as a respiratory syncytial virus (RSV) vaccine.

In older adults 65 years of age and older, Comirnaty XFG may be given at the same time as a high dose flu and an RSV vaccine.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine.

No data are available yet regarding the use of Comirnaty XFG during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen. Comirnaty XFG can be used during pregnancy.

No data are available yet regarding the use of Comirnaty XFG during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty XFG can be used while breast-feeding.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

3. How Comirnaty XFG is given

Comirnaty XFG is given as an injection of 0.3 mL into a muscle of your upper arm.

You will receive 1 injection, regardless whether you have received a COVID-19 vaccine before.

If you were previously vaccinated with a COVID-19 vaccine, you should not receive a dose of Comirnaty XFG until at least 3 months after the most recent dose.

If you are immunocompromised, you may receive additional doses of Comirnaty XFG.

If you have any further questions on the use of Comirnaty XFG, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty XFG can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people

- injection site: pain, swelling
- tiredness, headache
- muscle pain, joint pain
- chills, fever
- diarrhoea

Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.

Common side effects: may affect up to 1 in 10 people

- nausea
- vomiting ('very common' in pregnant women 18 years of age and older and in immunocompromised individuals 12 to 18 years of age)
- injection site redness ('very common' in immunocompromised individuals 12 years of age and older)
- enlarged lymph nodes (more frequently observed after a booster dose)

Uncommon side effects: may affect up to 1 in 100 people

- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- decreased appetite
- dizziness
- excessive sweating, night sweats

Rare side effects: may affect up to 1 in 1 000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10 000 people

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)

- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or “bulls-eye” with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Comirnaty XFG

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 6 hours.

Thawed (previously frozen) vials: Once removed from the freezer, the unopened vial may be stored and transported refrigerated at 2 °C to 8 °C for up to 10 weeks; not exceeding the printed expiry date (EXP). The outer carton should be marked with the new expiry date at 2 °C to 8 °C. Once thawed, the vaccine cannot be re-frozen.

Thawed vials can be handled in room light conditions.

Opened vials: Once the vaccine vial is punctured it should be used immediately or within 6 hours and kept at 2 °C to 8 °C. Discard any unused vaccine.

Do not use this vaccine if you notice particulates or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Comirnaty XFG contains

- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called mRNA encoding XFG.
 - A multidose vial contains 6 doses of 0.3 mL with 30 micrograms mRNA encoding XFG each.
- The other ingredients are:
 - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
 - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
 - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
 - cholesterol
 - trometamol
 - trometamol hydrochloride
 - sucrose
 - water for injections

What Comirnaty XFG looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in a multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal.

Multidose vials pack size: 10 vials

Manufacturer

BioNTech Manufacturing GmbH
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55131 Mainz
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Phone: +49 6131 9084-0
Fax: +49 6131 9084-2121
service@biontech.de

This leaflet was last revised in {MM/YYYY}

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

The following information is intended for healthcare professionals only:

Administer Comirnaty XFG intramuscularly as a single dose of 0.3 mL regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty XFG should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Additional doses may be given to individuals who are severely immunocompromised.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions prior to use for frozen vials

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Comirnaty XFG should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has a **grey plastic cap** and the product **name is Comirnaty XFG 30 micrograms/dose dispersion for injection** (12 years and older).
- If the vial has another product name on the label, please make reference to the WHO Product Information for that formulation.
- If the vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw. Ensure vials are completely thawed prior to use. A 10-vial pack of multidose vials may take 6 hours to thaw.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.
- Unopened vials can be **stored for up to 10 weeks at 2 °C to 8 °C**; not exceeding the printed expiry date (EXP).
- Thawed vials can be handled in room light conditions.

Preparation of 0.3 mL doses

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
 - Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
 - Withdraw 0.3 mL of Comirnaty XFG.
 - **Low dead-volume syringes and/or needles** should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead-volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
 - Each dose must contain 0.3 mL of vaccine.
 - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
 - Record the appropriate date/time on the vial. Discard any unused vaccine 6 hours after first puncture.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Package leaflet: Information for the user

Comirnaty XFG 30 micrograms/dose dispersion for injection (refrigerated only vials) Adults and adolescents from 12 years COVID-19 mRNA Vaccine mRNA encoding XFG

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Comirnaty XFG is and what it is used for
2. What you need to know before you receive Comirnaty XFG
3. How Comirnaty XFG is given
4. Possible side effects
5. How to store Comirnaty XFG
6. Contents of the pack and other information

1. What Comirnaty XFG is and what it is used for

Comirnaty XFG is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty XFG 30 micrograms/dose dispersion for injection is given to adults and adolescents from 12 years of age and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty XFG does not contain the virus to produce immunity, it cannot give you COVID-19.

The use of this vaccine should be in accordance with official recommendations.

2. What you need to know before you receive Comirnaty XFG

Comirnaty XFG should not be given

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given the vaccine if:

- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given this vaccine in the past.
- you are feeling nervous about the vaccination process or have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.

- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty XFG may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty XFG may be lower in people who are immunocompromised. If you are immunocompromised, you may receive additional doses of Comirnaty XFG. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Children

Comirnaty XFG 30 micrograms/dose dispersion for injection is not recommended for children aged under 12 years.

There are paediatric formulations available for infants aged 6 months and above and children below 12 years of age. For details, please refer to the WHO Package Leaflet for other formulations.

The vaccine is not recommended for infants aged under 6 months.

Other medicines and Comirnaty XFG

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Comirnaty XFG may be given at the same time as a flu vaccine.

In adults 18 years of age and older, Comirnaty XFG may be given at the same time as a pneumococcal conjugated vaccine (PCV).

In adults 18 years of age and older, Comirnaty XFG may be given at the same time as a respiratory syncytial virus (RSV) vaccine.

In older adults 65 years of age and older, Comirnaty XFG may be given at the same time as a high dose flu and an RSV vaccine.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine.

No data are available yet regarding the use of Comirnaty XFG during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen. Comirnaty XFG can be used during pregnancy.

No data are available yet regarding the use of Comirnaty XFG during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty XFG can be used while breast-feeding.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

3. How Comirnaty XFG is given

Comirnaty XFG is given as an injection of 0.3 mL into a muscle of your upper arm.

You will receive 1 injection, regardless whether you have received a COVID-19 vaccine before.

If you were previously vaccinated with a COVID-19 vaccine, you should not receive a dose of Comirnaty XFG until at least 3 months after the most recent dose.

If you are immunocompromised, you may receive additional doses of Comirnaty XFG.

If you have any further questions on the use of Comirnaty XFG, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty XFG can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people

- injection site: pain, swelling
- tiredness, headache
- muscle pain, joint pain
- chills, fever
- diarrhoea

Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.

Common side effects: may affect up to 1 in 10 people

- nausea
- vomiting ('very common' in pregnant women 18 years of age and older and in immunocompromised individuals 12 to 18 years of age)
- injection site redness ('very common' in immunocompromised individuals 12 years of age and older)
- enlarged lymph nodes (more frequently observed after a booster dose)

Uncommon side effects: may affect up to 1 in 100 people

- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- decreased appetite
- dizziness
- excessive sweating, night sweats

Rare side effects: may affect up to 1 in 1 000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10 000 people

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)

- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or “bulls-eye” with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Comirnaty XFG

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP.

Store in a refrigerator at 2 °C to 8 °C. DO NOT FREEZE.

Store in the original package in order to protect from light.

The vials can be handled in room light conditions.

Opened vials: Once the vaccine vial is punctured it should be used immediately or within 6 hours and kept at 2 °C to 8 °C. Discard any unused vaccine.

Do not use this vaccine if you notice particulates or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Comirnaty XFG contains

- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called mRNA encoding XFG. A multidose vial contains 6 doses of 0.3 mL with 30 micrograms mRNA encoding XFG each.
- The other ingredients are:
 - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
 - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
 - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
 - cholesterol
 - trometamol
 - trometamol hydrochloride
 - sucrose
 - water for injections

What Comirnaty XFG looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in a multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal.

Multidose vials pack size: 10 vials

Manufacturer

BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz
Germany
Phone: +49 6131 9084-0
Fax: +49 6131 9084-2121
service@biontech.de

This leaflet was last revised in {MM/YYYY}

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

The following information is intended for healthcare professionals only:

Administer Comirnaty XFG intramuscularly as a single dose of 0.3 mL regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty XFG should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Additional doses may be given to individuals who are severely immunocompromised.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions prior to use for refrigerated only vials

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Comirnaty XFG should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has a **grey plastic cap** and the product **name is Comirnaty XFG 30 micrograms/dose dispersion for injection** (12 years and older).
- If the vial has another product name on the label, please make reference to the WHO Product Information for that formulation.
- Unopened vials are **stored at 2 °C to 8 °C**; not exceeding the printed expiry date (EXP).
- The vials can be handled in room light conditions.

Preparation of 0.3 mL doses

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
- Multidose vials contain 6 doses of 0.3 mL each.
- Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty XFG.
- **Low dead-volume syringes and/or needles** should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead-volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 6 hours after first puncture.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Package leaflet: Information for the user

Comirnaty XFG 10 micrograms/dose dispersion for injection Infants and children 6 months to 11 years COVID-19 mRNA Vaccine mRNA encoding XFG

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects your child may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before your child receives this vaccine because it contains important information for your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor, pharmacist or nurse.
- If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Comirnaty XFG is and what it is used for
2. What you need to know before your child receives Comirnaty XFG
3. How Comirnaty XFG is given
4. Possible side effects
5. How to store Comirnaty XFG
6. Contents of the pack and other information

1. What Comirnaty XFG is and what it is used for

Comirnaty XFG is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty XFG 10 micrograms/dose dispersion for injection is given to infants and children from 6 months to 11 years of age.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty XFG does not contain the virus to produce immunity, it cannot give your child COVID-19.

The use of this vaccine should be in accordance with official recommendations.

2. What you need to know before your child receives Comirnaty XFG

Comirnaty XFG should not be given

- if your child is allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your child's doctor, pharmacist or nurse before your child is given the vaccine if your child:

- has ever had a severe allergic reaction or breathing problems after any other vaccine injection or after having been given this vaccine in the past.
- is feeling nervous about the vaccination process or has ever fainted following any needle injection.

- has a severe illness or infection with high fever. However, your child can have the vaccination if he/she has a mild fever or upper airway infection like a cold.
- has a bleeding problem, bruises easily or uses a medicine to prevent blood-clots.
- has a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects the immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty XFG may not fully protect all those who receive it and it is not known how long your child will be protected.

The efficacy of Comirnaty XFG may be lower in people who are immunocompromised. If your child is immunocompromised, he/she may receive additional doses of Comirnaty XFG. In these cases, your child should continue to maintain physical precautions to help prevent COVID-19. In addition, your child's close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your child's doctor.

Children

The vaccine is not recommended for infants aged under 6 months.

Other medicines and Comirnaty XFG

Tell your child's doctor or pharmacist if your child is using, has recently used or might use any other medicines or has recently received any other vaccine.

Pregnancy and breast-feeding

If your child is pregnant, tell your child's doctor, nurse or pharmacist before your child receives this vaccine.

No data are available yet regarding the use of Comirnaty XFG during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen.

Comirnaty XFG can be used during pregnancy.

No data are available yet regarding the use of Comirnaty XFG during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty XFG can be used while breast-feeding.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your child's ability to use machines or undertake activities such as cycling. Wait until these effects have worn off before resuming activities that require your child's full attention.

3. How Comirnaty XFG is given

Comirnaty XFG is given as an injection of 0.3 mL into a muscle of your child's upper arm.

Children 5 years to 11 years of age

Your child will receive 1 injection, regardless whether he/she has received a COVID-19 vaccine before.

If your child was previously vaccinated with a COVID-19 vaccine, he/she should not receive a dose of Comirnaty XFG until at least 3 months after the most recent dose.

Infants and children 6 months to 4 years of age

If your child has not received a COVID-19 vaccine in the past, your child will receive a maximum of 2 doses (the total number of doses required as a primary course). It is recommended to receive the second dose 8 weeks after the first dose to complete the primary course.

If your child turns 5 years old between their doses in the primary course, he/she should complete the primary course at the same 10 micrograms dose level.

If your child has previously completed a COVID-19 primary vaccination course, your child will receive 1 injection. If your child was previously vaccinated with a COVID-19 vaccine, your child should not receive a dose of Comirnaty XFG until at least 3 months after the most recent dose.

If your child has previously received 1 or 2 doses of the 3 micrograms 3-dose primary course but has not completed the COVID-19 primary vaccination course, he/she may receive additional doses of Comirnaty XFG 10 micrograms. The second dose may be administered 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose.

Immunocompromised infants and children 6 months to 11 years of age

If your child is immunocompromised, he/she may receive additional doses of Comirnaty XFG.

If you have any further questions on the use of Comirnaty XFG, ask your child's doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty XFG can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people

- irritability (6 months to less than 2 years)
- injection site: pain/tenderness, swelling
- tiredness, headache
- drowsiness (6 months to less than 2 years)
- muscle pain, joint pain
- chills, fever
- diarrhoea

Common side effects: may affect up to 1 in 10 people

- nausea
- vomiting ('very common' in pregnant women 18 years of age and older and in immunocompromised individuals 2 to 18 years of age)
- injection site redness ('very common' in 6 months to 11 years of age and in immunocompromised individuals 2 years of age and older)
- enlarged lymph nodes (more frequently observed after a booster dose)

Uncommon side effects: may affect up to 1 in 100 people

- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia

- injection site itching
- allergic reactions such as rash ('common' for 6 months to less than 2 years) or itching
- decreased appetite ('very common' for 6 months to less than 2 years)
- dizziness
- excessive sweating, night sweats

Rare side effects: may affect up to 1 in 1 000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10 000 people

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)

- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects

If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Comirnaty XFG

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

Single dose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of single dose vials of the vaccine can be thawed at 2 °C to 8 °C for 2 hours.

Multidose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of single dose vials of the vaccine can be thawed at 2 °C to 8 °C for 6 hours.

Thawed (previously frozen) vials: Once removed from the freezer, the unopened vial may be stored and transported refrigerated at 2 °C to 8 °C for up to 10 weeks; not exceeding the printed expiry date (EXP). The outer carton should be marked with the new expiry date at 2 °C to 8 °C. Once thawed, the vaccine cannot be re-frozen.

Thawed vials can be handled in room light conditions.

Opened vials: After the vaccine vial is first punctured it should be used immediately or within 6 hours and kept at 2 °C to 8 °C. Discard any unused vaccine.

Do not use this vaccine if you notice particulates or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Comirnaty XFG contains

- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called mRNA encoding XFG.
 - A single dose vial contains 1 dose of 0.3 mL with 10 micrograms of mRNA encoding XFG per dose.
 - A multidose vial contains 6 doses of 0.3 mL with 10 micrograms of mRNA encoding XFG per dose.
- The other ingredients are:
 - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
 - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
 - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
 - cholesterol
 - trometamol
 - trometamol hydrochloride
 - sucrose
 - water for injections

What Comirnaty XFG looks like and contents of the pack

The vaccine is a clear to slightly opalescent dispersion (pH: 6.9 - 7.9) provided in either:

- A single dose vial of 1 dose in a 2 mL clear vial (type I glass), with a rubber stopper and a blue flip-off plastic cap with aluminium seal; or
- A multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a blue flip-off plastic cap with aluminium seal.

Single dose vials pack size: 10 vials

Multidose vials pack size: 10 vials

Not all pack sizes may be marketed.

Manufacturer

BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz
Germany
Phone: +49 6131 9084-0
Fax: +49 6131 9084-2121
service@biontech.de

This leaflet was last revised in {MM/YYYY}

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

The following information is intended for healthcare professionals only:

Children 5 years to 11 years of age

Administer Comirnaty XFG intramuscularly as a single dose of 0.3 mL regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty XFG should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Infants and children 6 months to 4 years of age

If the child has not received a COVID-19 vaccine, administer Comirnaty XFG intramuscularly as a primary course of 2 doses of 0.3 mL. Administer the second dose 8 weeks after the first dose.

If the child has completed a COVID-19 vaccine primary course, administer Comirnaty XFG intramuscularly as a single dose of 0.3 mL. For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty XFG should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

If the child has received 1 or 2 doses of the 3 micrograms 3-dose primary series but has not completed the primary vaccination course, additional doses of Comirnaty XFG 10 micrograms may be given. The second dose may be administered 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose.

Immunocompromised infants and children 6 months to 11 years of age

Additional doses may be given to individuals who are severely immunocompromised.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions prior to use

The storage and handling conditions printed on the vial or carton labels may differ from those in this product information. In these circumstances, the conditions in the product information should be followed.

Comirnaty XFG should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has a **blue plastic cap** and the product **name is Comirnaty XFG 10 micrograms/dose dispersion for injection** (infants and children 6 months to 11 years).
- If the vial has another product name on the label, please make reference to the WHO Product Information for that formulation.
- If the vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw. Ensure vials are completely thawed prior to use.
 - Single dose vials: A 10-vial pack of single dose vials may take 2 hours to thaw.
 - Multidose vials: A 10-vial pack of multidose vials may take 6 hours to thaw.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.
- Unopened vials can be **stored for up to 10 weeks at 2 °C to 8 °C**; not exceeding the printed expiry date (EXP).
- Thawed vials can be handled in room light conditions.

Preparation of 0.3 mL doses

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
- Check whether the vial is a single dose vial or a multidose vial and follow the applicable handling instructions below:
 - Single dose vials
 - Withdraw a single 0.3 mL dose of vaccine.
 - Discard vial and any excess volume.
 - Multidose vials
 - Multidose vials contain 6 doses of 0.3 mL each.
 - Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
 - Withdraw 0.3 mL of Comirnaty XFG for infants and children aged 6 months to 11 years.
 - **Low dead-volume syringes and/or needles** should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead-volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
 - Each dose must contain 0.3 mL of vaccine.
 - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
 - Record the appropriate date/time on the vial. Discard any unused vaccine 6 hours after first puncture.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.