Vaxigrip

Suspension for injection in multidose vial
Trivalent influenza vaccine (split virion, inactivated)

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English

VAXIGRIP suspension for injection in multidose vial

Trivalent influenza vaccine (split virion, inactivated)

Read all of this leaflet carefully before you or your child are vaccinated 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 or nurse.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you or your child get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. WHAT VAXIGRIP IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: influenza vaccine — ATC code: J07BB02

VAXIGRIP is a vaccine.

This vaccine administered to you or your child from 6 months of age helps to protect you or your child against influenza (flu).

The use of VAXIGRIP should be based on official recommendations.

When a person is given the vaccine VAXIGRIP, the immune system (the body's natural defence system) will produce its own protection (antibodies) against the disease.

None of the ingredients in the vaccine can cause flu.

Flu is a disease that can spread rapidly and is caused by different types of strains that can change every year. Due to this potential change in circulating strains on a yearly basis, as well as the duration of protection expected of the vaccine, vaccination is recommended every year. The greatest risk of catching flu is during the cold months between October and March. If you or your child were not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you or your child run the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

VAXIGRIP is intended to protect you or your child against the three strains of virus contained in the vaccine from about 2 to 3 weeks after the injection.

In addition, if you or your child are exposed to flu immediately before or after your vaccination, you or your child could still develop the illness as the incubation period for flu is a few days.

The vaccine will not protect you or your child against the common cold, even though some of the symptoms are similar to flu.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE VAXIGRIP

To make sure that VAXIGRIP is suitable for you or your child, it is important to tell your doctor if any of the points below apply to you or your child.

If there is anything you do not understand, ask your doctor to explain.

Do not use VAXIGRIP:

- If you or your child are allergic to:
  - the active substances or
  - any of the other ingredients of this vaccine (listed in section 6) including thiomersal, or
  - any component that may be present in very small amounts such as eggs (ovalbumin or chicken proteins), neomycin, formaldehyde or octoxynol-9.

Warnings and precautions

Talk to your doctor or nurse before using VAXIGRIP.

You should tell your doctor before vaccination if you or your child have:

- experienced health problems following a previous administration of a vaccine.
- a poor immune response (immunodeficiency or taking medicines affecting the immune system),
- bleeding problems or bruise easily.

If you or your child have an illness with a high or moderate temperature or an acute illness, vaccination should be postponed until after recovery.

Fainting can occur following, or even before, any needle injection. Therefore, tell your doctor or nurse if you or your child fainted with a previous injection.

As with all vaccines, VAXIGRIP may not fully protect all persons who are vaccinated.

Children

VAXIGRIP is not recommended for use in children below 6 months of age.

Other medicines and VAXIGRIP

- Tell your doctor if you or your child are receiving, have recently received or might receive any other vaccines or any other medicines.
- VAXIGRIP can be given at the same time as other vaccines by using separate injection sites and on different limbs.
- The immunological response may decrease in case of immunosuppressive treatments, such as corticosteroids, cytotoxic drugs or radiotherapy.

Pregnancy and breast-feeding

There are no data from clinical studies on the use of VAXIGRIP that contains thiomersal in pregnant women.
Internationally, limited data on the use of vaccines containing thiomersal in pregnant women, including VAXIGRIPTETRA (quadrivalent influenza vaccine), have not identified any safety concerns.
More data are available concerning the use of inactivated influenza vaccines during the second and third trimesters of pregnancy than for the first trimester. However, international data on the use of inactivated influenza vaccines do not indicate harmful effects attributable to the vaccine for the foetus and mother.
These data agree with results observed in one clinical study conducted in Finland in which VAXIGRIP and VAXIGRIPTETRA (thiomersal-free vaccines) were administered in pregnant women.
One reproductive and developmental toxicity study performed in rabbits with VAXIGRIPTETRA containing thiomersal did not indicate direct or indirect harmful effects with respect to gestation, embryo-foetal development or early post-natal development.

The use of VAXIGRIP may consequently be considered during pregnancy.

The excretion of the vaccine into human milk is unknown.

VAXIGRIP can be administered during breast-feeding.

Driving and using machines

VAXIGRIP has no or negligible influence on the ability to drive and use machines.

VAXIGRIP contains potassium and sodium

This medicine contains less than 1 mmol potassium (39 mg) and sodium (23 mg) per dose, that is to say it is essentially ‘potassium-free’ and ‘sodium-free’.

3. HOW TO USE VAXIGRIP

Posology

Adults receive one 0.5 mL dose.

Use in children and adolescents

- Children from 6 months to 8 years of age receive two 0.5 mL doses at interval of at least 4 weeks if they have not been previously vaccinated against flu. When they have been previously vaccinated, children should receive only one 0.5 mL dose.

- Children from 9 years to 17 years of age receive one 0.5 mL dose.

How VAXIGRIP is given

Your doctor or nurse will administer the recommended dose of the vaccine as an injection into the muscle or under the skin.

For adults and children from 36 months of age: the preferred site for intramuscular injection is the deltoid muscle in the upper arm.

For children from 6 to 35 months of age: the preferred site for intramuscular injection is the anterolateral aspect of the thigh.

If you or your child use more VAXIGRIP than you should

It is not documented for VAXIGRIP containing thiomersal.
Cases of administration of more than the recommended dose have been reported with VAXIGRIP thiomersal-free.

In these cases, when side effects were reported, they were in line with what is described following the administration of the recommended dose (see Section 4).

If you have any further questions on the use of this product, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

If you experience an allergic reaction, contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away.

Allergic reactions

They can occur immediately after vaccine administration and may be life-threatening.
Symptoms may include:

- Rash, itching, difficulty breathing, shortness of breath, swelling of the face, lips, throat or tongue, low blood pressure, rapid heart rate and weak pulse, cold, clammy skin, dizziness, weakness or fainting (anaphylactic reaction, angioedema, shock).

Other symptoms may include:

- Areas of itchy, red, swollen and cracked skin (atopic dermatitis), redness and warmth of the face, hot flush, blood in the white of the eye (ocular hyperaemia), redness and irritation of the eye (conjunctivitis), throat irritation, sore throat, irritation inside the nose, runny nose, sneezing, stuffy nose, sinus or throat, numbness or pins and needles sensation in the mouth (oral paraesthesia), rash in the mouth (oral eruption), asthma.

These allergic reactions were reported as uncommon (may affect up to 1 in 100 people) to rare (may affect up to 1 in 1,000 people).

Additional side effects in adults and the elderly

Very common (may affect more than 1 in 10 people)

- Headache, muscular pain, generally feeling unwell (malaise) [(1)], pain at the injection site

[(1)] Common in the elderly

Common (may affect up to 1 in 10 people)

- Fever [(2)], shivering, reactions at the injection site: redness (erythema), hardness (induration), swelling

[(2)] Uncommon in the elderly

Uncommon (may affect up to 1 in 100 people)

- Swelling of the glands in the neck, armpit or groin (lymphadenopathy) [(3)], unusual weakness [(3)], tiredness, sleepiness [(4)], dizziness [(4)], increased sweating (hyperhidrosis) [(3)], joint pain [(1)], diarrhoea, feeling sick (nausea), reactions at the injection site: bruising, itching, warmth [(1)], discomfort

[(3)] Rare in the elderly [(4)] Rare in adults

Rare (may affect up to 1 in 1,000 people)

- Numbness or pins and needles sensation (paraesthesia), vomiting, decreased appetite, flu-like illness
- Decreased sensitivity (hypoaesthesia), abdominal pain, allergy at the injection site: only seen in adults.
- Peeled off skin (exfoliation) at the injection site: only seen in the elderly

Additional side effects in children from 3 to 17 years of age

Very common (may affect more than 1 in 10 people)

- Headache, muscular pain, generally feeling unwell, shivering, reactions at the injection site: pain, redness, swelling, hardness [5]

[5] Common in children from 9 to 17 years old.

Common (may affect up to 1 in 10 people)

- Fever, chills, bruising at the injection site

Uncommon (may affect up to 1 in 100 people)

- Tiredness, dizziness, diarrhoea, reactions at the injection site, itching, warmth
- Swelling of the glands in the neck, armpit or groin, abdominal pain, vomiting, restlessness, moaning, joint pain, crying: only seen in children from 3 to 8 years of age.
- Reduction in the number of certain types of particles in the blood called platelets; a low number of these can result in excessive bruising or bleeding (thrombocytopenia): only seen in a 3-year-old child.
- Unusual weakness, discomfort at the injection site: only seen in children from 9 to 17 years of age.

Additional side effects in children from 6 to 35 months of age

Very common (may affect more than 1 in 10 people)

- Irritability [6], vomiting [7], muscular pain [8], generally feeling unwell [8], fever, decrease of appetite [6], reactions at the injection site: tenderness, redness.
- Unusual crying, drowsiness: only seen in children less than 24 months of age
- Headache: only seen in children 24 months of age and older.

[6] Rare in children from 24 to 35 months old. [7] Uncommon in children from 24 to 35 months old. [8] Rare in children from 6 to 23 months old.

Common (may affect up to 1 in 10 people)

- Diarrhoea, reactions at the injection site: hardness (induration), bruising, swelling
- Shivering: only seen in children 24 months of age and older.

Rare (may affect up to 1 in 1,000 people)

- flu-like illness, reactions at the injection site: itching, rashes.

Most side effects usually occurred within the 3 days following vaccination and disappeared within 3 days without treatment. The intensity of most of these side effects was mild to moderate.

Side effects were generally less common in the elderly than in adults and children.

The frequency of the following side effects is not known (cannot be estimated from the available data) in the whole population except in the population for which the side effect is listed above:

- Swelling of the glands in the neck, armpit or groin
- Numbness or pins and needles sensation (paraesthesia), pain situated on the nerve route (neuralgia) [9], fits (convulsions)
- Neurological disorders that may result in stiff neck, confusion, numbness, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all the body (encephalomyelitis, neuritis [9] and Guillain-Barré Syndrome [9])
- Blood vessel inflammation (vasculitis) which may result in skin rashes and in very rare cases in temporary kidney problems
- Temporary reduction in the number of certain types of particles in blood called platelets; a low number of these can result in excessive bruising or bleeding (transient thrombocytopenia).

[9] Not reported in children from 6 to 35 months old

This vaccine contains thiomersal (an organomercury ingredient) which serves as a preservative; it is possible that you or your child may experience an allergic reaction.

Reporting of side effects

If you or your child get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE VAXIGRIP

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

Do not use this vaccine after the expiry date which is stated on the box after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the vial in the outer carton, in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your doctor 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 VAXIGRIP contains

- The active substances are: influenza virus (split, inactivated) of the following strains*:

A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238).....
.....15 micrograms HA**

A/Croatia/10136RV/2023 (H3N2)-like strain (A/Croatia/10136RV/2023, X-425A).....
.....15 micrograms HA**

B/Austria/1359417/2021-like strain (B/Michigan/01/2021, wild type).....
.....15 micrograms HA**

Per 0.5 mL dose

*Propagated in fertilised hens' eggs from healthy chicken flocks

**Haemagglutinin

This vaccine complies with the WHO (World Health Organization) recommendations (Northern Hemisphere) and European Union decision for the 2025/2026 season.

- The other ingredients are: thiomersal and a buffer solution containing sodium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate, potassium chloride, water for injections.

Some components such as egg derivatives (ovalbumin, chicken proteins), neomycin, formaldehyde or octoxynol-9 may be present as traces (see section 2).

What VAXIGRIP looks like and contents of the pack

The vaccine, after shaking gently, is a colourless opalescent liquid.

VAXIGRIP is a suspension which comes in a 5 mL multidose vial containing 10 doses, in a box of 10 vials.

Marketing Authorisation Holder

SANOFI WINTHROP INDUSTRIE
82 AVENUE RASPAIL
94250 GENTILLY
FRANCE

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The following information is intended for healthcare professionals only:

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

The vaccine should be allowed to reach room temperature before use.

Shake before use. Inspect visually prior to administration.

The vaccine should not be used if foreign particles are present in the suspension.

After first opening, the vaccine contained in the vial must be used within 28 days, stored between 2°C and 8°C and protected from light.

A new sterile syringe with a new sterile needle must be used for each dose taken and for each patient.

Between separate withdrawals and in all cases within 5 minutes of withdrawal of the last dose, the vial must be returned to the refrigerator so as to keep the product at the required storage temperature, i.e. between 2°C and 8°C (never in the freezer).

Any opened or partially used vials must be destroyed immediately:

- if the withdrawal was not completely sterile,
- if there is any possibility that the vial has been contaminated,
- if there is any visible sign of contamination, such as a change in appearance or the presence of particles in suspension.

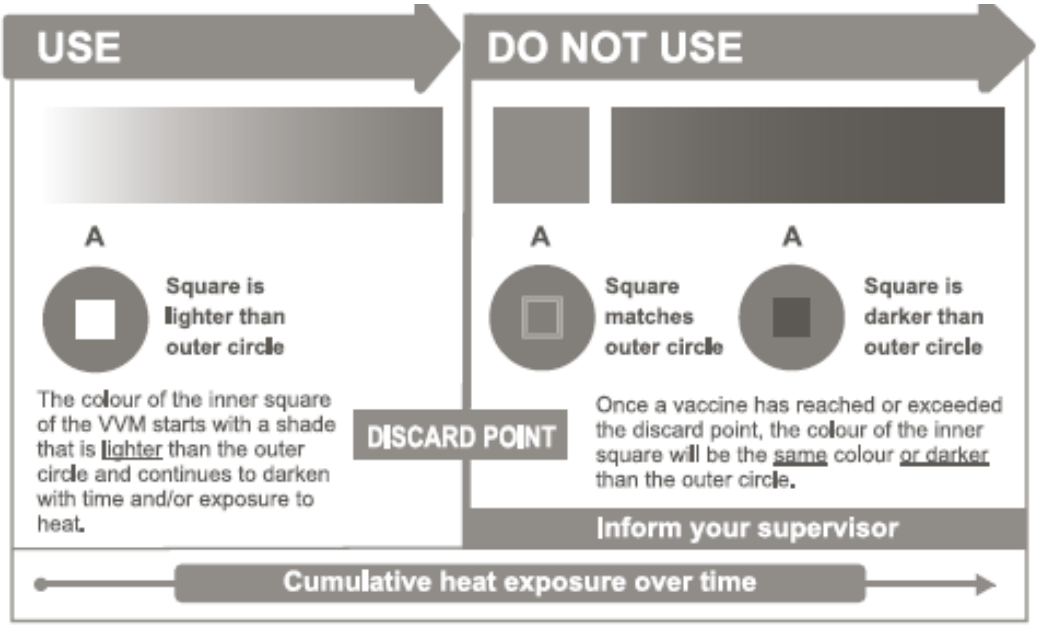
In all cases, the vial should be stored according to the conditions described in the manufacturer's instructions for use.

It should not be mixed with other medicinal products in the same syringe.

This vaccine must not be injected directly into a blood vessel.

See also section 3. How to use VAXIGRIP

The Vaccine Vial Monitors (VVM) are on the cap of VAXIGRIP vaccine supplied through SANOFI WINTHROP INDUSTRIE. The colour dot which appears on the cap of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.



The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the circle, then the vaccine can be used. As soon as the colour of the central square is the same colour as the circle or of a darker colour than the circle, then the vial should be discarded.