

PACKAGE LEAFLET: INFORMATION FOR THE USER

Focetria suspension for injection

Pandemic Influenza Vaccine (H1N1) (surface antigen, inactivated, adjuvanted)

For the most up-to-date information please consult the website of the European Medicines Agency (EMA):
<http://www.ema.europa.eu/>

Read all of this leaflet carefully before you receive this vaccine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Focetria is and what it is used for
2. Before you receive Focetria
3. How Focetria is given
4. Possible side effects
5. How to store Focetria
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1. WHAT FOCETRIA IS AND WHAT IT IS USED FOR

Focetria is a vaccine to prevent pandemic influenza (flu).

Pandemic flu is a type of influenza that occurs every few decades and which spreads rapidly around the world. The symptoms of pandemic flu are similar to those of an ordinary flu but may be more severe.

When a person is given the vaccine, the immune system (the body's natural defence system) will produce its own protection (antibodies) against the disease. None of the ingredient in the vaccine can cause flu.

2. BEFORE YOU RECEIVE FOCETRIA

You should not receive Focetria:

- if you have previously had a sudden life-threatening allergic reaction to any ingredient of Focetria (these are listed at the end of the leaflet) or to any of the substances that may be present in trace amounts as follows: egg and chicken protein, ovalbumin, formaldehyde, kanamycin and neomycin sulphate (antibiotics) or cetyltrimethylammonium bromide (CTAB). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue. However, in a pandemic situation, it may be appropriate for you to have the vaccine provided that appropriate medical treatment is immediately available in case of an allergic reaction.

If you are not sure, talk to your doctor or nurse before having this vaccine.

Take special care with Focetria:

- if you have had any allergic reaction other than a sudden life-threatening allergic reaction to any ingredient contained in the vaccine, to thiomersal (only for the multidose vial presentation), to egg and, chicken protein, ovalbumin, formaldehyde, kanamycin and neomycin sulphate (antibiotics) or cetyltrimethylammonium bromide (CTAB). (see section 6. Further information).
- if you have a severe infection with a high temperature (over 38°C). If this applies to you then your vaccination will usually be postponed until you are feeling better. A minor infection such as a cold

should not be a problem, but your doctor or nurse should advise whether you could still be vaccinated with Focetria,

- if you are having a blood test to look for evidence of infection with certain viruses. In the first few weeks after vaccination with Focetria the results of these tests may not be correct. Tell the doctor requesting these tests that you have recently been given Focetria.

In any of these cases, TELL YOUR DOCTOR OR NURSE, as vaccination may not be recommended, or may need to be delayed.

Please inform your doctor or nurse if you have a bleeding problem or bruise easily.

Taking other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or have recently been given any other vaccine. Focetria can be given at the same time as non-adjuvanted seasonal influenza vaccines, with injections made into separate limbs.

There is no information on administration of the vaccine Focetria with any other vaccines. However, if this cannot be avoided, the vaccines should be injected into separate limbs. In such cases, you should be aware that the side effects may be more intense.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you may be pregnant, plan to become pregnant. You should discuss with your doctor whether you should receive Focetria. The vaccine may be used during breast-feeding.

Driving and using machines

Some effects mentioned under section 4. "Possible side effects" may affect the ability to drive or use machines.

Important information about some of the ingredients of Focetria

This vaccine in a multi-dose vial contains thiomersal as a preservative and it is possible that you may experience an allergic reaction. Tell your doctor if you have any known allergies. This medicinal contains less than 1 mmol sodium (23 mg) and less than 1 mmol of potassium (39 mg) per 0.5 ml dose, i.e. essentially sodium- and potassium free.

3. HOW FOCETRIA IS GIVEN

Your doctor or nurse will administer the vaccine in accordance with official recommendations. The vaccine will be injected into a muscle (usually in the upper arm).

Adults

A dose (0.5 ml) of the vaccine will be given.

Clinical data suggest that a single dose may be sufficient.

If a second dose is administered there should be an interval of at least three weeks between the first and second dose.

Elderly:

A dose (0.5 ml) of the vaccine and a second dose of 0.5 ml at least three weeks later.

Children and adolescents 3-17 years of age:

You or your child will receive one dose of 0.5 ml vaccine.
Available clinical data suggest that a single dose may be sufficient.
If a second dose is administered there should be an interval of at least three weeks between the first and second dose.

Children 6 months to 35 months:

You or your child will receive one dose of 0.5 ml vaccine and a second dose of 0.5 ml at least three weeks later.

Children aged less than 6 months of age:

Vaccination is currently not recommended in this age group.

When Focetria is given for the first dose, it is recommended that Focetria (and not another vaccine against H1N1) be given for the complete vaccination course.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Focetria can cause side effects, although not everybody gets them.
Allergic reactions may occur following vaccination, in rare cases leading to shock. Doctors are aware of this possibility and have emergency treatment available for use in such cases.

In the clinical studies with the vaccine, most side effects were mild in nature and short term. The side-effects are generally similar to those related to the seasonal flu vaccine.

The frequency of possible side effects listed below is defined using the following convention:

very common (affects more than 1 user in 10)

common (affects 1 to 10 users in 100)

uncommon (affects 1 to 10 users in 1,000)

rare (affects 1 to 10 users in 10,000)

very rare (affects less than 1 user in 10,000)

The side effects listed below have occurred with Focetria in clinical studies in adults, including the elderly:

Very common:

Pain, hardening of the skin at the injection site, injection site redness, injection site swelling, pain at the site of injection, aching muscles, headache, sweating, fatigue, generally feeling unwell and shivering

Common:

Bruising of the skin at the injection site, fever and nausea

Uncommon:

Flu like symptoms

Rare:

Convulsion, eye swelling and anaphylaxis

These side effects usually disappear within 1-2 days without treatment. If they persist, CONSULT YOUR DOCTOR.

Side effects from clinical studies in children

A clinical study was conducted with a similar vaccine in children. General side effects reported very commonly in the 6 months-35 months of age group per dose were irritability, unusual crying, sleepiness, diarrhoea and change in eating habits. In children very common systemic events included headache, fatigue.

Among the adolescents the very common events were: generally feeling unwell, aching muscles, pain, headache, fatigue, sweating, nausea and chills.

Other side effects

The side effects listed below have occurred in the days or weeks after vaccination with Focetria.

Generalised skin reactions including itching, urticaria (hives), rash or swelling of the skin and mucous membranes.

Disorders of the gut such as nausea, vomiting, abdominal pain and diarrhoea.

Headache, dizziness, drowsiness, fainting.

Neurological disorders such as severe stabbing or throbbing pain along one or more nerves, tingling, fits, and neuritis (inflammation of nerves).

Swollen lymph nodes, palpitations, weakness, pain in the extremities and cough.

Allergic reactions possibly with shortness of breath, wheezing, swelling of the throat, or leading to a dangerous decrease of blood pressure, which, if untreated, may lead to shock. Doctors are aware of this possibility and have emergency treatment available for use in such cases.

Data for children and adolescents who received Focetria showed a comparable safety profile. Very commonly reported reactions were pain, hardening of the skin at the injection site, injection site redness, generally feeling unwell, myalgia, headache and fatigue.

Data in children and adolescents suggest a slight decrease in reactogenicity after the second dose of the vaccine, with no increase in rates of fever.

In addition, the side effects listed below have occurred in the days or weeks after vaccination with adjuvanted and non-adjuvanted vaccines given routinely every year to prevent flu. These side effects may occur with Focetria.

Rare:

Low blood platelet count which can result in bleeding or bruising.

Very rare:

Vasculitis (inflammation of the blood vessels which can cause skin rashes, joint pain and kidney problems), exudative erythema multiforme.

Neurological disorders such as encephalomyelitis (inflammation of the central nervous system), and a type of paralysis known as Guillain-Barré Syndrome.

If any of these side effects occur, please tell your doctor or nurse immediately.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE FOCETRIA

Keep out of the reach and sight of children.

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

Store in a refrigerator (2°C - 8°C).

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

Do not freeze.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Focetria contains

- Active Substance:
Influenza virus surface antigens (haemagglutinin and neuraminidase)* of strain:
A/California/7/2009 (H1N1)v like strain (X-181) 7.5 micrograms** per 0.5 ml dose

* propagated in eggs

** expressed in microgram haemagglutinin.

This vaccine complies with the WHO recommendation and EU decision for the pandemic.

- Adjuvant:
The vaccine contains an 'adjuvant' (MF59C.1) to stimulate a better response. MF59C.1 is an oil/water emulsion containing 9.75 mg squalene, 1.175 mg polysorbate 80 and 1.175 mg sorbitan trioleate in a citrate buffer. Quantities are expressed per 0.5 ml vaccine dose.
- Other Ingredients:
The other ingredients are: thiomersal (multidose vial only), sodium chloride, potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, magnesium chloride hexahydrate, calcium chloride dihydrate, sodium citrate, citric acid and water for injections.

What Focetria looks like and contents of the pack

Focetria is a milky-white liquid.

It is provided in:

- a ready-to-use syringe, containing a single dose of 0.5 ml for injection;
- vial containing ten doses of 0.5 ml each for injection.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Novartis Vaccines and Diagnostics S.r.l.
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Italy.

Manufacturer

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Italy.

The following information is intended for medical or healthcare professionals only:

Instructions for administration of the vaccine:

Ready-to-use syringe, containing a single dose of 0.5 ml for injection:

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

Gently shake before use.

Vial containing ten doses (0.5 ml each) for injection:

Gently shake the multidose vial each time before withdrawing a dose (0.5 ml) of the vaccine into a syringe. Prior to administration, the withdrawn vaccine should be allowed to reach room temperature.

Although Focetria in multidose vials contains a preservative that inhibits microbial growth, minimisation of the risk of contamination of the multidose vial during withdrawal of each dose is the responsibility of the user.

Record date and time of the first dose withdrawal on the vial label.

Between uses, return the multidose vial to the recommended storage conditions between 2° and 8° C (36° and 46° F). The multidose vial should preferably be used within 24 hours after first withdrawal.

Preliminary data are also available that suggest that multidose vials could be used up to a maximum of 72 hours after first withdrawal, although such pro-longed storage periods should not be the preferred option.

The vaccine should not be administered intravascularly.

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

This leaflet was last approved in

Focetria has been authorised under “Exceptional Circumstances”. The European Medicines Agency (EMA) will regularly review any new information on the medicine and this package leaflet will be updated as necessary.

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.ema.europa.eu/>