

CORE PACKAGE LEAFLET FOR TRIVALENT INFLUENZA VACCINES

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PACKAGE LEAFLET: INFORMATION FOR THE USER
<Product name>, suspension for injection in <Product specific>
Influenza vaccine <common name>

Read all of this leaflet carefully before you or your child is vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist
- This vaccine has been prescribed for you or your child. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

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1. WHAT <PRODUCT NAME> IS AND WHAT IT IS USED FOR

<Product name> is a vaccine. This vaccine helps to protect you or your child against influenza (flu), particularly in subjects who run a high risk of associated complications. The use of <Product name> should be based on official recommendations.

When a person is given the vaccine <Product name>, 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. Therefore, this is why you might need to be vaccinated every year. The greatest risk of catching flu is during the cold months between October and March. If you or your child was not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you or your child runs the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

<Product name> will protect you or your child against the three strains of virus contained in the vaccine from about 2 to 3 weeks after the injection.

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

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

2. BEFORE <YOU> OR <YOUR CHILD> USE <PRODUCT NAME>

To make sure that <Product name> is suitable for you or your child, it is important to tell your doctor or pharmacist if any of the points below apply to you or your child. - If there is anything you do not understand, ask your doctor or pharmacist to explain.

Do not use <Product name>

- If you or your child is allergic (hypersensitive) to the active substances, to any of the ~~excipients~~ingredients of <Product name>, ~~<to eggs>~~, ~~<to chicken proteins>~~, ~~<to thiomersal (if the vaccine contains thiomersal as preservative)>~~, to <-Product specific residue: e.g. eggs, chicken proteins, such as ovalbumin > (For other ingredients of <Product name>, see section 6 "Further information").
- If you or your child has an illness with a high temperature or acute infection, the vaccination shall be postponed until after you or your child has recovered.

Take special care with <Product name>

You should tell your doctor before vaccination if you or your child has a poor immune response (immunodeficiency or taking medicines affecting the immune system).

Your doctor will decide if you or your child should receive the vaccine.

If, for any reason, you or your child has a blood test within a few days following a flu vaccination, please tell your doctor. This is because false positive blood test results have been observed in a few patients who had recently been vaccinated.

As with all vaccines, <Product name> may not fully protect all persons who are vaccinated.

Using other medicines

- Please tell your doctor or pharmacist if you or your child is taking or has recently taken other vaccines or any other medicines, including medicines obtained without a prescription.
- <Product name> can be given at the same time as other vaccines by using separate limbs. It should be noted that the side effects may be stronger.
- The immunological response may decrease in case of immunosuppressant treatment, such as corticosteroids, cytotoxic drugs or radiotherapy.

Pregnancy and breast-feeding

Tell your doctor or pharmacist if you are pregnant or think you may be pregnant.

Limited data from flu vaccinations in pregnant women do not indicate that the vaccine would have harmful effects on the pregnancy or the baby. The use of this vaccine may be considered from the second trimester of pregnancy. For pregnant women with medical conditions that increase their risk of complications from the flu, administration of the vaccine is recommended, irrespective of their stage of pregnancy.

<Product name> may be used during breast-feeding.

Your doctor/pharmacist will be able to decide if you should receive <Product name>.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

The vaccine is unlikely to affect your ability to drive or use machines.

Important information about some of the ingredients of <Product name>

<Product specific>

3. HOW TO USE <PRODUCT NAME>

Dosage

Adults and children aged from 36 months receive one 0.5 ml dose.

Children from 6 months to 35 months may receive one 0.25 ml dose or one 0.5 ml dose.

If your child has not been previously vaccinated against flu, a second dose should be given after at least 4 weeks.

Method and/or route(s) of administration

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, <Product name> can cause side effects, although not everybody gets them.

During clinical trials, the following side effects have been observed. Their frequencies have been estimated as Common: affects 1 to 10 users in 100.

- headache
- sweating
- muscular pain (myalgia), joint pain (arthralgia)
- fever, generally feeling unwell (malaise), shivering, fatigue
- local reactions: redness, swelling, pain, bruising (ecchymosis), hardness (induration) around the area where the vaccine is injected.

These reactions usually disappear within 1-2 days without treatment.

Next to the above common side effects, the following side effects occurred after the vaccine came on the market:

- allergic reactions:
 - leading to medical emergency with a failure of the circulatory system to maintain adequate blood flow to the different organs (shock) in rare cases,
 - swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body (angioedema) in very rare cases.
- skin reactions that may spread throughout the body including itchiness of the skin (pruritus, urticaria), rash
- blood vessel inflammation which may result in skin rashes (vasculitis) and in very rare cases in temporary kidney problems.
- pain situated on the nerve route (neuralgia), anomalies in the perception of touch, pain, heat and cold (paraesthesia), fits (convulsions) associated with fever, 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, Guillain-Barré Syndrom)
- temporary 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 (transient thrombocytopenia); temporary swelling of the glands in the neck, armpit or groin (transient lymphadenopathy)

If thiomersal is used as preservative or in the manufacturing process which results in levels of thiomersal \geq 40 ng per dose, the following should be mentioned:

<This medicinal product contains thiomersal as a preservative/Thiomersal is present (in trace amounts) in this product> and it is possible that <you/your child> may experience an allergic reaction. Tell your doctor if <you/your child> have/has any known allergies.

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

5. HOW TO STORE <PRODUCT NAME>

Keep out of the reach and sight of children.

Do not use <Product name> after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

<Product specific storage conditions>

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

~~The active substance is <Product specific>*~~ <Whole influenza virus (inactivated)> <Influenza virus (inactivated, split)> <Influenza virus surface antigens (haemagglutinin and neuraminidase)> of the following strains*:

A/<Official strain> (H1N1) ~~*** like strain (<actual strain>)~~ <n>micrograms HA**

A/<Official strain> (H3N2) ~~*** like strain (<actual strain>)~~ <n>micrograms HA**

B/<Official strain> ~~*** like strain (<actual strain>)~~ <n>micrograms HA**

Per <Product specific> ml dose

* ___ propagated in fertilised hens' eggs from healthy chicken flocks

** ___ haemagglutinin

*** **When the official strain is directly used: nothing added.**

When the strain used is like to the official one: - like strain used <actual strain >.

When the strain used is derived from the official one: derived strain used <actual strain >.

When the strain used is derived from a strain like to the official one: - like strain used <actual strain> derived from <like strain>.

This vaccine complies with the WHO (World Health Organisation) recommendations (Northern hemisphere) and EU decision for the yyyy/yyyy season.

The other ingredients are <Product specific>

What <Product name> looks like and contents of the pack

<Product name> is {pharmaceutical form} presented (in {container} (content) {content of the package}

<Product specific>

Marketing Authorisation Holder and Manufacturer

<Manufacturer specific>

This medicinal product is authorised in the Member States of the EEA under the following names:

<Product specific>

This leaflet was last approved in {MM/YYYY}.

<Product specific>

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