

PACKAGE LEAFLET

Package leaflet: Information for the user

Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose suspension for injection in pre-filled syringe

Is this leaflet hard to see or read? Phone 0845 372 7101 for help.

▼ 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 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, pharmacist or nurse.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- 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

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1. What Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose is and what it is used for

Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose is a vaccine. This vaccine helps to protect persons of 65 years of age and older against influenza (flu). The use of Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose should be based on official recommendations.

When a person is given Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose, 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 intended by the vaccine, vaccination is recommended every year. The greatest risk of catching flu is during the cold months between October and March. If you were not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you run the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose is intended to protect you against the three strains of virus contained in the vaccine about 2 to 3 weeks after the injection. In addition, if you are exposed to flu immediately before or after your vaccination, you could still develop the illness as the incubation period for flu is a few days.

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

2. What you need to know before you use Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose

To make sure that Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose is suitable for you, it is important to tell your doctor or pharmacist if any of the points below apply to you. If there is anything you do not understand, ask your doctor or pharmacist to explain.

Do not use Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose:

- if you are allergic to:
 - the active substances, or
 - any of the other ingredients of this vaccine (listed in Section 6), or
 - any component that may be present in very small amounts such as eggs (ovalbumin, chicken proteins), formaldehyde and octoxinol-9,
- if you have an illness with a high or moderate temperature or an acute infection, the vaccination should be postponed until after you have recovered.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose.

You should tell your doctor before vaccination if you have:

- a poor immune response (immunodeficiency or taking medicines affecting the immune system),
- bleeding problem or bruising easily.

Your doctor will decide if you should receive the vaccine.

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

As with all vaccines, Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose may not fully protect all persons who are vaccinated.

If, for any reason, you have 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.

Children

This vaccine is only for use in adults aged 65 years and older.

Other medicines and Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose

Tell your doctor or pharmacist if you are receiving, have recently received or might receive any other vaccines or any other medicines.

- If Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose needs to be given at the same time as other vaccines, the vaccines should always be administered in separate limbs, and it should be noted that the side effects may be more intense.
- The immunological response may decrease in case of immunosuppressant treatment, such as corticosteroids, cytotoxic drugs or radiotherapy.

Pregnancy and breast-feeding

Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose is only indicated for use in adults aged 65 years and older.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this vaccine. Your doctor/pharmacist will help you decide if you should receive Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose.

Driving and using machines

Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose has no or negligible influence on the ability to drive or use machines.

Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose contains sodium

This medicine contains less than 1mmol sodium (3.3 mg) per dose, i.e. essentially 'sodium-free'.

3. How to use Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose

Adults aged 65 years and over receive one 0.5 ml dose.

How Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose is given

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

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

4. Possible side effects

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

Allergic reactions

See a doctor **IMMEDIATELY** if you experience:

- Severe allergic reactions:
 - that may lead to medical emergency with low blood pressure, rapid, shallow breathing, rapid heart rate and weak pulse, cold, clammy skin, dizziness, that may lead to collapse (shock).
 - swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body and which may cause difficulty in swallowing or breathing (angioedema).

See a doctor if you experience:

- Allergic reactions such as skin reactions that may spread throughout the body including itching, hives, rash, redness.

Other side effects reported

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

- Reactions at the injection site: pain, redness (erythema)
- Generally feeling unwell (malaise), headache, muscular pain (myalgia)

Common (may affect up to 1 in 10 people):

- Swelling at the injection site, fever

Uncommon (may affect up to 1 in 100 people):

- Reactions at the injection site: bruising, hardness (induration)
- Chills, fatigue, feeling sick (nausea), diarrhoea, vomiting, dizziness, cough, pain in extremities
- Swelling of the glands in the neck, armpit or groin (lymphadenopathy)

Rare (may affect up to 1 in 1000 people):

- Flushing, pruritus

Not known: frequency cannot be estimated from the available data

- 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)
- Numbness or pins and needles sensation (paraesthesia),
- 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 and transverse myelitis, neuritis, Guillain-Barré Syndrome), fits (convulsions including febrile convulsions), fainting (syncope) shortly after vaccination
- Blood vessel inflammation (vasculitis) which may result in skin rashes and in very rare cases in temporary kidney problems, blood vessel opening (vasodilatation)
- Joint pain (arthralgia)
- Abnormal lack of energy (asthenia), chest pain
- Excess of blood in the white of the eye (ocular hyperaemia)
- Inflammation of the throat and the nose (pharyngitis, rhinitis), wheezing, throat tightness, difficulty breathing (dyspnea).

Most side effects usually occurred within the 3 days following vaccination, and resolved within 3 days. The intensity of these side effects was mild to moderate.

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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

United Kingdom

Medicines and Healthcare products Regulatory Agency (MHRA): Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose

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 label and carton after EXP.

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

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

6. Contents of the pack and other information

What Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose contains

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

A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09 - like strain
(A/Guangdong-Maonan/SWL1536/2019, CNIC-1909).....60 micrograms HA**

A/Hong Kong/2671/2019 (H3N2) - like strain (A/Hong Kong/2671/2019, IVR-208)
.....60 micrograms HA**

B/Washington/02/2019 - like strain (B/Washington/02/2019, wild type)
.....60 micrograms HA**

Per 0.5 ml dose

* propagated in embryonated chicken eggs and inactivated with formaldehyde

** haemagglutinin

This vaccine complies with the WHO (World Health Organisation) recommendations (Northern Hemisphere) and EU decision for the 2020/2021 season.

The other ingredients are: a buffer solution containing sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate and water for injections. It also contains an excipient, octoxinol-9.

Some components such as eggs (ovalbumin, chicken proteins) or formaldehyde may be present in very small amounts (see Section 2).

What Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose looks like and contents of the pack

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

Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose is a sterile aqueous suspension for injection presented in a pre-filled syringe of 0.5 ml, without needle, in box of 5 or 10. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:

Sanofi Pasteur
410 Thames Valley Park Drive
Reading
Berkshire
RG6 1PT
UK

The Manufacturer is:

Sanofi Pasteur
Parc Industriel d'Incarville
27100 VAL DE REUIL
France

This leaflet was last revised in 06/2020.

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.

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

This vaccine is not to be injected directly into a blood vessel.

See also Section 3. How to use Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose