

Package leaflet: Information for the user

Quadrivalent Influenza Vaccine (split virion, inactivated), suspension for injection in pre-filled syringe

Quadrivalent influenza vaccine (split virion, inactivated)

▼ 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 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, pharmacist 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Quadrivalent Influenza Vaccine (split virion, inactivated) is and what it is used for
2. What you need to know before you or your child use Quadrivalent Influenza Vaccine (split virion, inactivated)
3. How to use Quadrivalent Influenza Vaccine (split virion, inactivated)
4. Possible side effects
5. How to store Quadrivalent Influenza Vaccine (split virion, inactivated)
6. Contents of the pack and other information

1. What Quadrivalent Influenza Vaccine (split virion, inactivated) is and what it is used for

Quadrivalent Influenza Vaccine (split virion, inactivated) is a vaccine. This vaccine helps to protect you or your child against influenza (flu). The use of Quadrivalent Influenza Vaccine (split virion, inactivated) should be based on official recommendations.

When a person is given Quadrivalent Influenza Vaccine (split virion, inactivated), 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 or your child 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.

Quadrivalent Influenza Vaccine (split virion, inactivated) is intended to protect you or your child against the four strains of virus contained in the vaccine 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 or your child use Quadrivalent Influenza Vaccine (split virion, inactivated)

To make sure that Quadrivalent Influenza Vaccine (split virion, inactivated) 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 Quadrivalent Influenza Vaccine (split virion, inactivated):

- if you or your child 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), neomycin, formaldehyde or octoxinol-9,
- if you or your child have an illness with a high or moderate temperature or an acute illness, the vaccination should be postponed until after you or your child have recovered.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Quadrivalent Influenza Vaccine (split virion, inactivated).

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

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

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

Fainting can occur (mostly in adolescents) 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, Quadrivalent Influenza Vaccine (split virion, inactivated) may not fully protect all persons who are vaccinated.

If, for any reason, you or your child 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

Quadrivalent Influenza Vaccine (split virion, inactivated) is not recommended for use in children below 3 years of age.

Other medicines and Quadrivalent Influenza Vaccine (split virion, inactivated)

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

- Quadrivalent Influenza Vaccine (split virion, inactivated) can be given at the same time as other vaccines by using separate limbs.
- The immunological response may decrease in case of immunosuppressant treatment, such as corticosteroids, cytotoxic drugs or radiotherapy.

Pregnancy and breast-feeding

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 be able to decide if you should receive Quadrivalent Influenza Vaccine (split virion, inactivated).

Driving and using machines

Quadrivalent Influenza Vaccine (split virion, inactivated) has no or negligible influence on the ability to drive or use machines.

Quadrivalent Influenza Vaccine (split virion, inactivated) contains potassium and sodium

This medicine contains less than 1 mmol potassium (39 mg) and sodium (23 mg) per dose, i.e. essentially 'potassium-free' and 'sodium-free'.

3. How to use Quadrivalent Influenza Vaccine (split virion, inactivated)

Dosage

Adults receive one 0.5 ml dose.

Use in children

Children from 3 to 17 years of age receive one 0.5 ml dose.

If your child is less than 9 years old and has not been previously vaccinated against flu, a second dose of 0.5 ml should be given after at least 4 weeks.

How Quadrivalent Influenza Vaccine (split virion, inactivated) is given

Your doctor or nurse will administer the recommended dose of the vaccine as an injection into the muscle or 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, this vaccine can cause side effects, although not everybody gets them.

Allergic reactions

See a doctor IMMEDIATELY if you or your child 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). These side effects were not observed with Quadrivalent Influenza Vaccine (split virion, inactivated) but have been rarely reported with other vaccines given to prevent flu (may affect up to 1 in 1,000 people).
 - 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).
- Allergic reactions such as skin reactions that may spread throughout the body including itching, hives, rash, redness.
These side effects are rare (may affect up to 1 in 1,000 people) except itching (pruritus) that may be more frequent (may affect up to 1 in 100 people).

Other side effects reported in adults and elderly

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

- Headache, muscular pain (myalgia), generally feeling unwell (malaise)⁽¹⁾, injection site pain.

Common (may affect up to 1 in 10 people)

- Fever⁽²⁾, shivering, injection site reactions: redness, swelling, hardness (induration).

Uncommon (may affect up to 1 in 100 people)

- Dizziness⁽³⁾, diarrhoea, feeling sick (nausea)⁽⁴⁾, fatigue, injection site reactions: bruising (ecchymosis), itching (pruritus), warmth.
- Hot flush: observed in elderly only.
- Swelling of the glands in the neck, armpit or groin (lymphadenopathy): observed in adults only.

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

- Anomalies in the perception of touch, pain, heat and cold (paraesthesia), sleepiness, increased sweating (hyperhidrosis), unusual tiredness and weakness (asthenia), flu-like illness
- Joint pain (arthralgia), injection site discomfort: observed in adults only.

⁽¹⁾ Common in elderly ⁽²⁾ Uncommon in elderly ⁽³⁾ Rare in adults ⁽⁴⁾ Rare in elderly

Other side effects reported in children from 3 to 17 years of age

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

- Headache, muscular pain (myalgia), generally feeling unwell (malaise), shivering ⁽⁵⁾, injection site reactions: pain, swelling, redness ⁽⁵⁾, hardness (induration) ⁽⁵⁾.

Common (may affect up to 1 in 10 people)

- Fever, injection site bruising (ecchymosis).

Uncommon (may affect up to 1 in 100 people) in children from 3 to 8 years of age

- 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 thrombocytopaenia): reported in one child of 3 years of age.
- Moaning, restlessness.
- Dizziness, diarrhoea, vomiting, upper abdominal pain, joint pain (arthralgia), fatigue, injection site warmth.

Uncommon (may affect up to 1 in 100 people) in children from 9 to 17 years of age

- Diarrhoea, injection site itching (pruritus).

⁽⁵⁾ Common in children from 9 to 17 years of age

In children from 3 to 8 years of age who receive 2 doses, side effects are similar after the first and after the second dose.

When observed, side effects generally occurred within the first 3 days following vaccination and resolved spontaneously within 1 to 3 days after onset. The intensity of observed side effects was mild. Overall, side effects were generally less frequent in elderly than in adults and children from 3 to 17 years of age.

The following side effects have been reported after administration of Inactivated Influenza Vaccine (Split Virion) BP. These side effects may occur with Quadrivalent Influenza Vaccine (split virion, inactivated):

- Pain situated on the nerve route (neuralgia), 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, Guillain-Barré syndrome).
- Blood vessel inflammation (vasculitis) which may result in skin rashes and in very rare cases in temporary kidney problems.

Reporting of side effects

If you or your child 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.

Ireland

Health Products Regulatory Authority (HPRA): HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store Quadrivalent Influenza Vaccine (split virion, inactivated)

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. The expiry date refers to the last day of that month.

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 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 Quadrivalent Influenza Vaccine (split virion, inactivated) contains

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

A/Michigan/45/2015 (H1N1)pdm09 - like strain (A/Michigan/45/2015, NYMC X-275)..... 15 micrograms HA**

A/Hong Kong/4801/2014 (H3N2) - like strain (A/Hong Kong/4801/2014, NYMC X-263B)..... 15 micrograms HA**

B/Brisbane/60/2008 - like strain (B/Brisbane/60/2008, wild type)..... 15 micrograms HA**

B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, 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 Organisation) recommendations (Northern Hemisphere) and EU decision for the 2017/2018 season.

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

Some components such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde or octoxinol-9 may be present in very small amounts (see Section 2).

What Quadrivalent Influenza Vaccine (split virion, inactivated) looks like and contents of the pack

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

Quadrivalent Influenza Vaccine (split virion, inactivated) is a suspension for injection presented in a pre-filled syringe of 0.5 ml, with attached needle or without needle, in box of 1, 10 or 20. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:

Sanofi Pasteur Europe
2 Avenue Pont Pasteur
69007 Lyon
France

The distributor is:

United Kingdom:
Sanofi
One Onslow Street
Guildford
Surrey
GU1 4YS
UK
Tel: 0845 372 7101

Ireland:

sanofi-aventis Ireland T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland
Tel: +353 (0) 1 4035 600

The Manufacturer is:

Sanofi Pasteur - 1541 avenue Marcel Mérieux - 69280 Marcy l'Etoile - France
Sanofi Pasteur - Parc Industriel d'Incarville - 27100 Val de Reuil - France
Sanofi Aventis Zrt. - Campona utca 1. (Harbor Park) - 1225 Budapest - Hungary

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

<u>Member State</u>	<u>Name</u>
Austria	VaxigripTetra Injektionssuspension in einer Fertigspritze
Lithuania	VaxigripTetra injekcinė suspensija užpildytame švirkšte
Bulgaria, Croatia, Cyprus, Estonia, Finland, France, Greece, Iceland, Latvia, Malta, Poland, Portugal, Romania, Slovenia, Sweden, Netherlands	VaxigripTetra
Denmark, Norway	Vaxigriptetra
Belgium, Luxemburg	Vaxigrip Tetra suspension injectable en seringue préremplie
Germany, Italy, Spain, Czech Republic, Slovakia, Hungary	Vaxigrip Tetra

Ireland, United Kingdom	Quadrivalent Influenza Vaccine (split virion, inactivated)
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This leaflet was last revised in 07/2017.

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 Quadrivalent Influenza Vaccine (split virion, inactivated)