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)

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

Quadrivalent Influenza Vaccine (split virion, inactivated) 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).

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. When given during pregnancy the vaccine helps to protect the pregnant women but also helps to protect her baby from birth to less than 6 months of age through the transmission of protection from mother to baby during pregnancy (see also Sections 2 and 3).

None of the ingredients in the vaccine can cause flu.

The use of Quadrivalent Influenza Vaccine (split virion, inactivated) should be based on official recommendations.

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.

Not all babies less than 6 months of age born to pregnant women vaccinated during pregnancy will be protected.

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 6 months 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, or think you may be pregnant, ask your doctor or pharmacist for

advice before using this vaccine.

Quadrivalent Influenza Vaccine (split virion, inactivated) can be used in all stages of pregnancy.

Quadrivalent Influenza Vaccine (split virion, inactivated) may be used during breast-feeding.

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 less than 1 mmol sodium (23 mg) per dose, that is to say 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 6 months 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.

If you are pregnant, one 0.5 mL dose given to you during pregnancy may protect your baby from birth to less than 6 months of age. Ask your doctor or pharmacist for more information.

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 or your child receive more Quadrivalent Influenza Vaccine (split virion, inactivated) than you should
In some cases, more than the recommended dose has been inadvertantly administered.
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 or pharmacist.

4. Possible side effects

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

Allergic reactions
Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away if you or your child experience allergic reactions (reported as rare: may affect up to 1 in 1,000 people) that can be life threatening.
Symptoms may include rash, itching, hives, redness, difficulty breathing, shortness of breath, swelling of the face, lips, throat, or tongue, cold, clammy skin, palpitations, dizziness, weakness or fainting.

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)], pain at the injection site.

[(1)] Common in elderly

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

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

[(2)] Uncommon in elderly

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

- Dizziness [(3)], diarrhoea, feeling sick (nausea) [(4)], fatigue, reactions at the injection site: bruising (ecchymosis), itching (pruritus), and warmth.

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

- Hot flush: only seen in the elderly.
- Swelling of the glands in the neck, armpit or groin (lymphadenopathy): only seen in adults.

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), discomfort at the injection site: only seen in adults.

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)], reactions at the injection site: pain, swelling, redness (erythema) [(5)], hardness (induration) [(5)].

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

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

- Fever, bruising (ecchymosis) at the injection site.

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

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

- Diarrhoea, itching (pruritus) at the injection site.

Other side effects reported in children from 6 to 35 months of age

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

- Vomiting [(1)], muscular pain (myalgia) [(2)], irritability [(3),] appetite lost [(3)], generally feeling unwell (malaise) [(2)], fever.

[(1)] Uncommon in children from 24 to 35 months of age [(2)] Rare in children less than 24 months of age
[(3)] Rare in children from 24 to 35 months of age

- Reactions at the injection site: pain/tenderness, redness (erythema).
- Headache: only seen in children from 24 months of age.
- Drowsiness, unusual crying: only seen in children less than 24 months of age.

Common (may affect up to 1 in 10 people):
- Shivering: only seen in children 24 months and older.
- Reactions at the injection site: hardness (induration), swelling, bruising (ecchymosis).

Uncommon (may affect up to 1 in 100 people):
- Diarrhoea, hypersensitivity.

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

- Flu-like illness, reactions at the injection site: rash, pruritus (itching).

In children from 6 months to 8 years of age who receive 2 doses, side effects are similar after the first and after the second dose. Fewer side effects may happen after the second dose in children from 6 to 35 months of age.

When seen, side effects generally happen in the first 3 days after the vaccination and go away by themselves in 1 to 3 days after they start. The intensity of observed side effects was mild.
Overall, side effects were generally less frequent in elderly than in adults and children.

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.
- Transient thrombocytopenia, lymphadenopathy, paraesthesia in other age groups than those described above for these side effects.

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: Health Products Regulatory Authority (HPRA) Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

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

A/Thailand/8/2022 (H3N2)-like strain
(A/California/122/2022, SAN-022).....15 micrograms HA**

B/Austria/1359417/2021-like strain
(B/Michigan/01/2021, 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 2024/2025 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) or with safety needle (in box of 1 or 10). Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:

Sanofi Pasteur Europe
14 Espace Henry Vallée
69007 Lyon
France

The distributor is:
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:

Member State	**Name**
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)

This leaflet was last revised in 06/2024.

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)

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.>