VaxigripTetra

Suspension for injection in pre-filled syringe

QUADRIVALENT INFLUENZA VACCINE
(SPLIT VIRION, INACTIVATED)
2025 season

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side affects 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 VaxigripTetra is and what it is used for

Pharmacotherapeutic group: influenza vaccine - ATC code: J07BB02.

VaxigripTetra 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 VaxigripTetra, the immune system (the body's natural defense system) will produce its own protection (antibodies) against the disease. When administered during pregnancy the vaccine helps to protect the pregnant women but also helps to protect her baby(ies) 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 VaxigripTetra 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. For Thailand the greatest risk of catching flu is during rainy season around June to September and in winter season in December to March of every year. Your doctor will be able to recommend the best time to be vaccinated.

VaxigripTetra 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 from flu as the incubation period for flu is a few days.

The vaccination 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 VaxigripTetra

To make sure that VaxigripTetra 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 VaxigripTetra:

- 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 VaxigripTetra. 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, VaxigripTetra 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

VaxigripTetra is not recommended for use in children below 6 months of age.

Other medicines and VaxigripTetra

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.

- VaxigripTetra 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 baby, ask your doctor or pharmacist for advice before using this vaccine.

VaxigripTetra can be used in all stages of pregnancy.

VaxigripTetra may be used during breast-feeding.

Your doctor/ pharmacist will be able to decide if you should receive VaxigripTetra.

Driving and using machines

VaxigripTetra has no or negligible influence on the ability to drive or use machines.

VaxigripTetra 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 it is essentially potassium-free and sodium-free.

3. How to use VaxigripTetra

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 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 administered 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 VaxigripTetra 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 VaxigripTetra than you should

In some cases, more than the recommended dose has been inadvertently 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 a healthcare professional immediately or go to the nearest hospital emergency room immediately 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, muscle pain (myalgia), 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), diarrhea, nausea (4), fatigue, reactions at the injection site: bruising (ecchymosis), itching (pruritus), 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 (paresthesia), 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), 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 blood elements called platelets; a low number of these can result in excessive bruising or bleeding (transient thrombocytopenia): only seen in one child of 3 years of age.
- Moaning, restlessness
- Dizziness, diarrhea, 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:

- Diarrheoa, 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 received 2 doses, side effects were 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 happening 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.

Side effects were generally less frequent in elderly than in adults and children.

The following side effects have been reported after administration of Vaxigrip. These side effects may occur with VaxigripTetra.

- pain situated on the nerve route (neuralgia), 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store VaxigripTetra

Keep 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 VaxigripTetra 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/Croatia/10136RV/2023 (H3N2)-like strain (A/Croatia/10136RV/2023, X-425A)…….. 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 Organization) recommendations (Southern Hemisphere) for the 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).

VaxigripTetra is inactivated with formaldehyde solution.
VaxigripTetra does not contain more than 0.05 microgram ovalbumin per dose.

What VaxigripTetra looks is and contents of the pack

The vaccine, after shaking gently, is a colourless opalescent liquid.
VaxigripTetra is a suspension for injection presented in a prefilled syringe of 0.5 ml, with attached needle or without needle, (in box of 1, 10 or 20) or with separate safety needle (in box of 1 or 10).
Not all pack sizes may be marketed.

Marketing Authorisation Holder

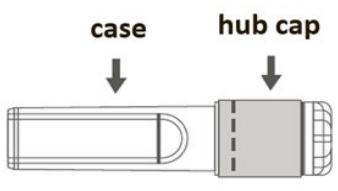
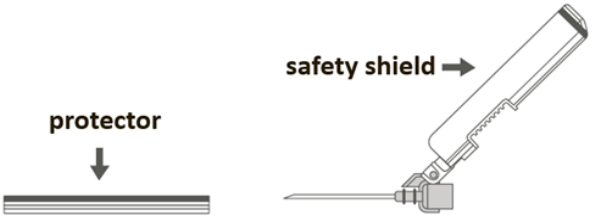
SANOFI PASTEUR LTD., Bangkok, Thailand

This leaflet was last revised in: 04/2025.

The following information is intended for healthcare professionals only:
As with all injectable vaccines, appropriate medical treatment and supervision should 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 VaxigripTetra.

Preparation for administration:

Instructions for use of Safety Needle with Luer Lock pre-filled syringe:

Picture A: Safety Needle (inside case)	**Picture B: Safety Needle Components (prepared for use)**
	

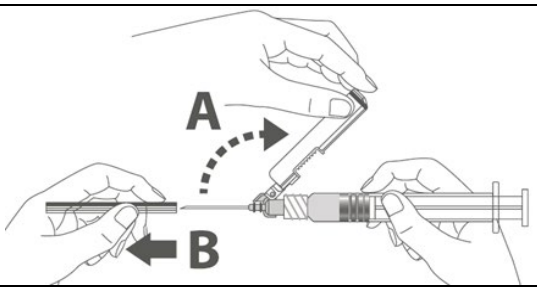
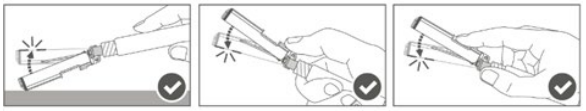
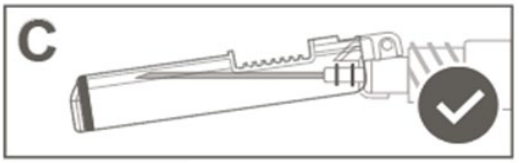
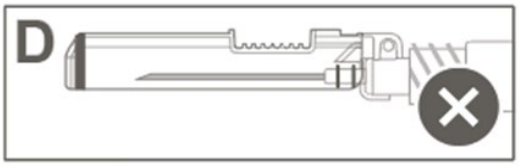
<table>
<tr><td colspan="2">Step 1: To attach the needle to the syringe, remove the hub cap to expose the hub of the needle and gently twist the needle into the Luer Lock adapter of the syringe until slight resistance is felt.</td></tr>
<tr><td colspan="2">Step 2: Pull the safety needle’s case straight off. The needle is covered by the safety shield and protector.</td></tr>
<tr><td>Step 3:
A: Move the safety shield away from the needle and toward the syringe barrel to the angle shown.
B: Pull the protector straight off.</td><td> 
</td></tr>
<tr><td>Step 4: After injection is complete, lock (activate) the safety shield using one of the three (3) one-handed techniques illustrated: surface, thumb or finger activation.
Note: Activation is verified by an audible and/or tactile “click.”</td><td>  </td></tr>
<tr><td>Step 5: Visually inspect the safety shield activation. The safety shield should be fully locked (activated) as shown in Figure C.

Figure D shows the safety shield is NOT fully locked (not activated).</td><td> 

 
</td></tr>
<tr><td colspan="2">Caution: Do not attempt to unlock (deactivate) the safety device by forcing the needle out of the safety shield.</td></tr>
</table>

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