PACKAGE LEAFLET: INFORMATION FOR THE USER

Vaxigrip suspension for injection in pre-filled syringe.

Trivalent 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 Vaxigrip is and what it is used for
2. What you need to know before you or your child use Vaxigrip
3. How to use Vaxigrip
4. Possible side effects
5. How to store Vaxigrip
6. Contents of the pack and other information

1. What Vaxigrip is and what it is used for

Vaxigrip 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 the vaccine Vaxigrip, 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 Vaxigrip 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 or your child run the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

Vaxigrip is intended to protect you or your child against the three strains of virus contained in the vaccine from 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 Vaxigrip

To make sure that Vaxigrip 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 Vaxigrip

- 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 or chicken proteins), neomycin, formaldehyde or octoxinol-9,

Warnings and precautions

Talk to your doctor or pharmacist before using Vaxigrip.

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.

If you or your child have an acute illness with fever, the vaccination should be postponed until the fever is resolved.

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, Vaxigrip 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.

Children

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

Other medicines and Vaxigrip

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.

- Vaxigrip can be given at the same time as other vaccines by using separate injection sites.
- 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, ask your doctor or pharmacist for advice before using this medicine.

Vaxigrip can be used in all stages of pregnancy.

Vaxigrip may be used during breast-feeding.

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

Driving and using machines

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

Vaxigrip 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 Vaxigrip

Dosage
Adults receive one 0.5 mL dose.

Use in children and adolescents
Children from 6 months to 17 years of age receive one 0.5 mL dose.

If your child is less than 9 years of age 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 Vaxigrip 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 Vaxigrip 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.

If you experience an allergic reaction, contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away.

Allergic reactions
They can occur immediately after vaccine administration and may be life-threatening.

Symptoms may include:
- Rash, itching, difficulty breathing, shortness of breath, swelling of the face, lips, throat or tongue, low blood pressure, rapid heart rate and weak pulse, cold, clammy skin, dizziness, weakness or fainting (anaphylactic reaction, angioedema, shock).

Other symptoms may include:
- areas of itchy, red, swollen, and cracked skin (dermatitis atopic), flushing, hot flush, blood in the white of the eye (ocular hyperaemia), redness and irritation of the eye (conjunctivitis), throat irritation, sore throat, irritation inside the nose, runny nose, sneezing, stuffy nose, sinus or throat, numbness or pins and needles sensation in the mouth (paraesthesia oral), rash in the mouth (oral mucosal eruption), asthma.

These allergic reactions were reported as uncommon (may affect up to 1 in 100 people) to rare (may affect up to 1 in 1 000 people).

Additional side effects in adults and elderly
Very common (may affect more than 1 in 10 people):
- Headache, muscular pain, 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), hardness (induration), swelling

[2] Uncommon in elderly

Uncommon (may affect up to 1 in 100 people):
- Swelling of the glands in the neck, armpit or groin (lymphadenopathy) [3], unusual weakness [3], tiredness, sleepiness [4], dizziness [4], increased sweating (hyperhidrosis) [3], joint pain [3], diarrhoea, feeling sick (nausea), reactions at the injection site: bruising, itching, warmth, discomfort

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

Rare (may affect up to 1 in 1 000 people):
- Numbness or pins and needles sensation (paraesthesia), vomiting, decreased appetite, flu-like illness
- Decrease sensitivity (hypoesthesia), abdominal pain, allergy at the injection site: only seen in adults.
- Peeled off skin (exfoliation) at the injection site: only seen in elderly.

Additional side effects in children from 3 to 17 years of age

Very common (may affect more than 1 in 10 people):
- Headache, muscular pain, generally feeling unwell, shivering, reactions at the injection site: pain, redness, swelling, hardness [5]

[5] Common in children from 9 to 17 years old

Common (may affect up to 1 in 10 people):
- Fever, bruising at the injection site

Uncommon (may affect up to 1 in 100 people):
- Tiredness, dizziness, diarrhoea, reactions at the injection site: itching, warmth
- Swelling of the glands in the neck, armpit or groin, abdominal pain, vomiting, restlessness, moaning, joint pain, crying: only seen in children from 3 to 8 years of age.
- 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): only seen in one child of 3 years of age.
- Unusual weakness, discomfort at the injection site: only seen in children from 9 to 17 years of age.

Additional side effects in children from 6 to 35 months of age

Very common (may affect more than 1 in 10 people):
- Irritability [6], vomiting [7], muscular pain [8], generally feeling unwell [8], fever, decrease of appetite [6], reactions at the injection site: tenderness, redness
- Unusual crying, drowsiness: only seen in children less than 24 months of age.
- Headache: only seen in children from 24 months of age

[6] Rare in children from 24 to 35 months old
[7] Uncommon in children from 24 to 35 months old
[8] Rare in children from 6 to 23 months old

Common (may affect up to 1 in 10 people):
- Diarrhoea, reactions at the injection site: hardness, bruising, swelling
- Shivering: only seen in children from 24 months of age.

Rare (may affect up to 1 in 1 000 people):
- Flu-like illness, reactions at the injection site: itching, rash

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.

Most side effects usually occurred within the 3 days following vaccination and disappeared within 1 to 3 days without treatment. The intensity of most these side effects was mild to moderate.

The frequency of the following side effects is not known (cannot be estimated from the available data) in the whole population except in the population for which the side effect is listed above:
- Swelling of the glands in the neck, armpit or groin

- Numbness or pins and needles sensation (paraesthesia), pain situated on the nerve route (neuralgia) [9], 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 [9], Guillain-Barré Syndrome [9])
- Blood vessel inflammation (vasculitis) which may result in skin rashes and in very rare cases in temporary kidney problems
- 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).

[9] Not reported in children from 6 to 35 months old

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 HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vaxigrip

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 Vaxigrip contains

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

A/Missouri/11/2025 (H1N1)pdm09-like strain
(A/Switzerland/6849/2025, IVR-278).....15 micrograms HA**

A/Darwin/1454/2025 (H3N2)-like strain
(A/Michigan/105/2025, SAN-049A).....15 micrograms HA**

B/Tokyo/EIS13-175/2025-like strain
(B/Tokyo/EIS13-175/2025, 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 2026/2027 season.

The other ingredients are: a buffer solution containing sodium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate, potassium chloride, 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 Vaxigrip looks like and contents of the pack

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

Vaxigrip is a suspension for injection presented in a pre-filled syringe of 0.5 mL, with attached needle, with separate needle or safety needle, or without 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 Winthrop Industrie
82 avenue Raspail
94250 Gentilly
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 Winthrop Industrie - 1541, avenue Marcel Mérieux - 69280 Marcy l'Etoile - France
Sanofi Winthrop Industrie - Voie de l'Institut - Parc Industriel d'Incarville B.P 101 – 27100 Val de Reuil - France
Sanofi-Aventis Zrt. - Building Dc5 - Campona Utca 1 - Budapest XXII,1225 - Hungary

This medicine is authorised in the Member States of the European Economic Area under the following names:

Member State	**Name**
Austria, Belgium, Bulgaria, Croatia, Czech Republic, Germany, Denmark, Estonia, Finland, France, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, Spain	Vaxigrip
Cyprus, Greece	Vaxigrip TIV

This leaflet was last revised in 06/2026.

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.

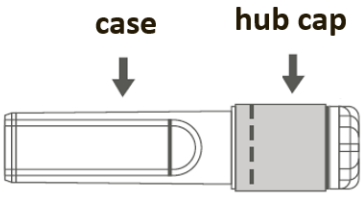
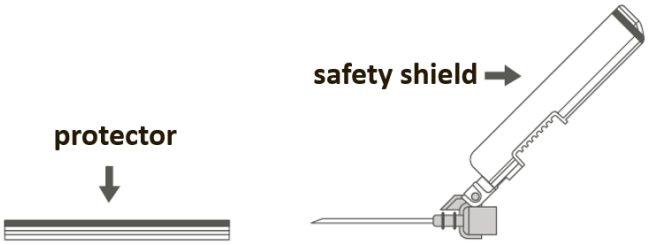
It should not be mixed with other medicinal products in the same syringe.

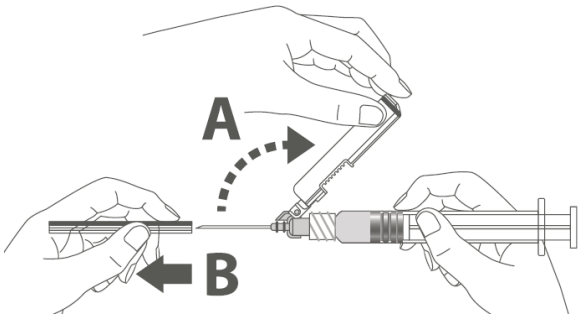
This vaccine is not to be injected directly into a blood vessel.

See also Section 3. How to use Vaxigrip

<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)**
	

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.	
Step 2: Pull the safety needle's case straight off. The needle is covered by the safety shield and protector.	
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.	

<table>
<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.

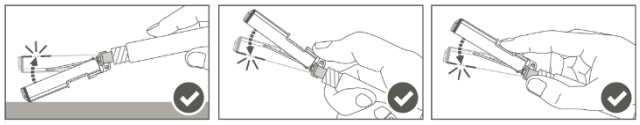
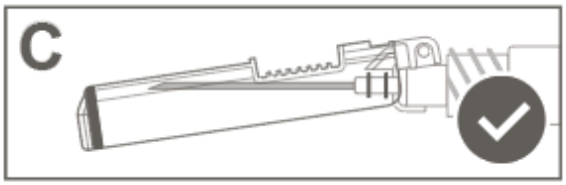
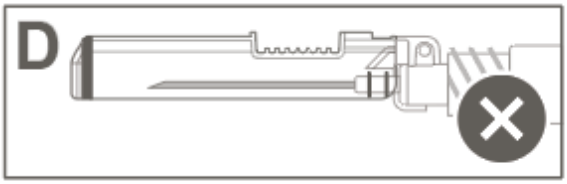
Note: Activation is verified by an audible and/or tactile “click.”</td><td></td></tr>
<tr><td>Step 5: Visually inspect the safety shield activation. The safety shield should be fully locked (activated) as shown in Figure C.

Figure D shows the safety shield is <u>NOT</u> 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>
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Any unused medicinal product or waste material should be disposed of in accordance with local requirements.