Vaxigrip®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Vaxigrip?

Vaxigrip is a vaccine. This vaccine helps to protect you or your child against influenza (flu). Vaxigrip is used to prevent flu in persons of 6 months of age and older.
If you are pregnant, one dose of vaccine given to you during pregnancy may protect your baby from birth to less than 6 months of age.

For more information, see Section 1. Why am I using Vaxigrip? in the full CMI.

2. What should I know before I am given Vaxigrip?

Do not use if you have ever had an allergic reaction to Vaxigrip or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given Vaxigrip? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Vaxigrip and affect how it works. Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other vaccines or medicines, including medicines obtained without a prescription.

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How is Vaxigrip given?

Vaxigrip is given by your doctor, nurse or pharmacist.

More instructions can be found in Section 4. How is Vaxigrip given? in the full CMI.

5. What should I know about after being given Vaxigrip?

Things you should do	Call your doctor straight away if:

	you notice signs of allergic reaction may include difficulty breathing, shortness of breath, swelling of the face, lips, throat or tongue, rapid heart rate and weak pulse, cold, clammy skin, palpitations, dizziness, weakness, fainting, rash or itching.
Looking after your medicine	Vaxigrip is usually stored in the surgery or clinic, or at the pharmacy. However, if you need to store Vaxigrip: • keep in the fridge between 2-8°C. Do not freeze.

For more information, see Section 5. What should I know about after being given Vaxigrip? in the full CMI.

6. Are there any side effects?

Serious side effects can include severe allergic reactions, pain situated on the nerve route, fits, 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 of the body and blood vessel inflammation which may

result in skin rashes and in very rare cases temporary kidney problems. **See your doctor immediately if you notice this.**

Common side effects include pain, tenderness, redness, swelling, bruising and hardness at the injection site, headache, muscle aches, feeling unwell, fever, and shivering. In children, other common side effects include irritability, abnormal crying, drowsiness, appetite loss and vomiting. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Vaxigrip®

Active ingredient(s): Influenza virus haemagglutinin

Consumer Medicine Information (CMI)

This leaflet provides important information about using Vaxigrip. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Vaxigrip.**

This vaccine can be given to adults and children so you may be reading this leaflet for you or for your child.

Where to find information in this leaflet:

1. Why am I using Vaxigrip?
2. What should I know before I am given Vaxigrip?
3. What if I am taking other medicines?
4. How is Vaxigrip given?
5. What should I know about after being given Vaxigrip?
6. Are there any side effects?
7. Product details

1. Why am I using Vaxigrip?

Vaxigrip contains the active ingredient influenza virus haemagglutinin.

Vaxigrip is a vaccine for persons 6 months of age and older. This vaccine helps to protect you or your child against influenza (flu). If you are pregnant, one dose of vaccine given to you during pregnancy may protect your baby from birth to less than 6 months of age.

When a person is given the vaccine, the immune system (the body's natural defence system) will produce its own protection against the influenza virus. 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. This is why you need to be vaccinated every year. The greatest risk of catching flu is during the cold months between June and September. 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.

As with all vaccines, Vaxigrip may not fully protect all persons who are vaccinated.

2. What should I know before I am given Vaxigrip?

Warnings

Do not use Vaxigrip:

- if you are allergic to the active ingredients or any of the ingredients listed at the end of this leaflet.

Symptoms of allergic reaction may include 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, palpitations, dizziness, weakness, fainting, rash or itching. If you are not sure if you are allergic, talk to your doctor, nurse or pharmacist before you receive Vaxigrip.

Always check the ingredients to make sure you can receive this vaccine.

Tell your doctor, nurse or pharmacist:

- If you have an acute illness with or without high temperature.
- If you have or have had an immune response problem because the immune response to the vaccine may be diminished.
- If you have a bleeding problem or bruise easily.
- If you have ever fainted from an injection. Fainting, sometimes with falling, can occur during, following, or even before, any injection with a needle.
- If you have or have had Guillain-Barré syndrome (severe muscle weakness) after getting a flu vaccine.
- If you have a known allergy to egg protein.

After vaccination, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of having Vaxigrip during pregnancy or breastfeeding.

Vaxigrip can be used in all stages of pregnancy.

Vaxigrip may be used during breast-feeding.

Due to the known adverse consequences of influenza infection in pregnant women, health authorities recommend vaccination for pregnant women.

Your doctor should make sure the benefits of vaccination outweigh the risks when recommending Vaxigrip.

3. What if I am taking other medicines?

Some medicines may interfere with Vaxigrip and affect how it works. Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other vaccines or medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor will advise you if Vaxigrip is to be given with another vaccine.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Vaxigrip.

4. How is Vaxigrip given?

How much is given

Vaxigrip is given by your doctor, nurse or pharmacist as a 0.5 mL injection in the muscle in the upper arm (preferably). For infants, the injection is normally given into the muscle of the thigh.

Children less than 9 years old, who have not been vaccinated against influenza before require a second injection a month later. Doses of influenza vaccine for infants and young children are decided by your doctor based on the official national recommendations.

5. What should I know about after being given Vaxigrip?

Things you should do

Call your doctor straight away if:

You notice signs of allergic reaction may include difficulty breathing, shortness of breath, swelling of the face, lips, throat or tongue, cold, clammy skin, palpitations, dizziness, weakness, fainting, rash or itching.

Driving or using machines

Do not drive or use machines if you are feeling unwell after vaccination. Wait until any effects of the vaccine have worn off before you drive or use machines.

Looking after your medicine

Vaxigrip is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Vaxigrip:

- keep it where young children cannot reach it.
- keep Vaxigrip in the original pack until it is time for it to be given.
- keep it in the refrigerator, store at 2°C to 8°C. Do not freeze Vaxigrip.

Do not use Vaxigrip after the expiry date which is stated on the carton after EXP.

Do not use Vaxigrip if the packaging is torn or shows signs of tampering.

Getting rid of any unwanted medicine

Medicines including vaccines should not be disposed of via wastewater or household waste. Ask your doctor, nurse or pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• pain, tenderness, redness, swelling, bruising and hardness at the injection site • feeling unwell • headache • dizziness • muscle aches • joint pain • fever • shivering • diarrhoea • nausea • excessive sweating • hot flush (in elderly)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• chest tightness (in adults) • irritability, abnormal crying, drowsiness, appetite loss, vomiting (in children) • temporary reduction in the number of blood particles called platelets (thrombocytopenia), swollen glands in neck, armpit or groin (lymphadenopathy)	

Serious side effects

Serious side effects	What to do
• pain situated on the nerve route (neuralgia), fits (convulsions) with or without fever, neurological disorders that may result in stiff neck • tingling or numbness of the hands or feet (paraesthesia) • confusion, numbness, pain and weakness	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
of the limbs, loss of balance, loss of reflexes, paralysis of part or all of the body (encephalomyelitis, neuritis, Guillain-Barre syndrome) • blood vessel inflammation (vasculitis) which may result in skin rashes and in very rare cases temporary kidney problems • severe allergic reaction (anaphylaxis)	

Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

What Vaxigrip contains

Active ingredient **(main ingredient)**	Influenza virus haemagglutinin of the following strains • A/Missouri/11/2025 (H1N1)pdm09-like strain (A/Switzerland/6849/2025, IVR-278) • A/Darwin/1454/2025 (H3N2)-like strain (A/Michigan/105/2025, SAN-049A) • B/Tokyo/EIS13-175/2025-like strain (B/Tokyo/EIS13-175/2025, wild type)
Other ingredients **(inactive ingredients)**	Sodium chloride, potassium chloride, dibasic sodium phosphate dihydrate, monobasic potassium phosphate, water for injections, and traces of ovalbumin (egg protein), neomycin,

	octoxinol-9 and formaldehyde.
Potential allergens	Vaxigrip may contain less than 0.05 microgram ovalbumin (egg protein) per dose.

Do not take this vaccine if you are allergic to any of these ingredients.

Vaxigrip syringes are not made with natural rubber latex.

What Vaxigrip looks like

Vaxigrip suspension for injection is clear and slightly opalescent in colour.

Vaxigrip is available in packs of 1 or 10 single dose (0.5 mL) pre-filled syringes with one separate needle or no needle provided per syringe.

AUST R 465534 – prefilled syringe needle free *

*Not all pack sizes may be marketed.

Who distributes Vaxigrip

Distributed by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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