Fluzone®

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, nurse or pharmacist.

1. Why am I using Fluzone?

Fluzone is a vaccine. This vaccine helps to protect you against influenza (flu). Fluzone is used to prevent flu in persons of 6 months of age and older.

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

2. What should I know before being given Fluzone?

Do not use if you have ever had an allergic reaction to Fluzone 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 being given Fluzone? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fluzone 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 Fluzone given?

Fluzone is given by your doctor, nurse or pharmacist.

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

5. What should I know about being given Fluzone?

Things you should do	Tell your doctor, nurse or pharmacist after you or your child receive the vaccine • have signs of allergic reactions that 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.
Looking after your medicine	Fluzone is usually stored in the surgery or clinic, or at the pharmacy. However, if you need to store Fluzone: • keep in the fridge between 2-8°C. Do not freeze.

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

6. Are there any side effects?

Serious side effects can include severe allergic reactions, inflammation of nerves leading to weakness, fainting, dizziness, tingling or numbness of hands or feet, temporary inflammation of nerves, fits, temporary reduction in the number of platelets, swollen glands in neck, armpit or groin. **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, cough, runny nose 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.

Fluzone®

Active ingredient(s): *Influenza virus haemagglutinin*

Consumer Medicine Information (CMI)

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

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

1. Why am I using Fluzone?

Fluzone contains the active ingredient influenza virus haemagglutinin.

Fluzone is a vaccine for persons 6 months of age and older. This vaccine helps to protect you against influenza (flu).

When a person is given the vaccine, the immune system (the body's natural defense system) will produce its own protection against the influenza virus. None of the ingredients in the vaccine can cause the flu.

Flu is a disease that can spread rapidly and is caused by different types of strains that can change every year. Therefore, this is why you might 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 influenza until then. Your doctor will be able to recommend the best time to be vaccinated.

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

2. What should I know before being given Fluzone?

Warnings

Do not use Fluzone:

- 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, 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 Fluzone.

  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 Fluzone during pregnancy or breastfeeding. 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 Fluzone.

3. What if I am taking other medicines?

Some medicines may interfere with Fluzone 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 Fluzone is to be given with another vaccine.

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

4. How is Fluzone given?

How much is given

Fluzone 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 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 being given Fluzone?

Things you should do

Call your doctor straight away if:

You notice signs of allergic reaction which 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

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

- keep it where young children cannot reach it.
- keep Fluzone 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 Fluzone.

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

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

Getting rid of 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 • muscle aches • fever • shivering • irritability, abnormal crying, drowsiness, appetite loss, cough, runny nose, vomiting (in children)	**Speak to your doctor, nurse or pharmacist if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• inflammation of nerves leading to weakness, such as weakness of facial muscles (facial palsy) or visual disturbance (optic neuritis/neuropathy) • fainting (syncope), dizziness, tingling or numbness of hands or feet (paraesthesia) • temporary inflammation of nerves causing pain, paralysis and sensitivity disorders (Guillain Barre syndrome [GBS]) • fits (convulsions) with or without fever • severe allergic reaction (anaphylaxis) • temporary reduction in the number of blood particles called platelets (thrombocytopenia), swollen glands in neck, armpit or groin (lymphadenopathy)	**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.**

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 in Australia or in New Zealand at https://nzphvc.otago.ac.nz/reporting. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

What Fluzone 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/Singapore/GP20238/2024 (H3N2)-like strain

	(A/Singapore/GP20238/2024, IVR-277) • B/Austria/1359417/2021- like strain (B/Michigan/01/2021, wild type)
Other ingredients (inactive ingredients)	Sodium chloride, dibasic sodium phosphate, monobasic sodium phosphate, water for injection, and traces of ovalbumin (egg protein), octoxinol-9 and formaldehyde.
Potential allergens	Fluzone contains less than 1 microgram ovalbumin (egg protein) per dose.

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

Fluzone does not contain any antibiotics or preservative.

Fluzone syringes are not made with natural rubber latex.

What Fluzone looks like

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

Fluzone is available in packs of 5 single dose (0.5 mL) pre-filled syringes with or without separate needles. Not all packs may be marketed.

Who distributes Fluzone

Distributed in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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