Fluzone® High-Dose Quadrivalent

Consumer Medicine Information (CMI) summary

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

1. Why am I using Fluzone High-Dose Quadrivalent?

Fluzone High-Dose Quadrivalent is a vaccine. This vaccine is recommended to help protect against influenza (flu) and associated pneumonia in persons aged 60 years and older.

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

2. What should I know before I am given Fluzone High-Dose Quadrivalent?

Do not use if you have ever had an allergic reaction to Fluzone High-Dose Quadrivalent or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions or take any other medicines.

For more information, see Section 2. What should I know before I am given Fluzone High-Dose Quadrivalent? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fluzone High-Dose Quadrivalent and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is Fluzone High-Dose Quadrivalent given?

Fluzone High-Dose Quadrivalent is administered to you by a health care professional.

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

5. What should I know about being given Fluzone High-Dose Quadrivalent?

Things you should do	Tell your doctor, nurse or pharmacist if you notice • 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 vaccine	Fluzone High-Dose Quadrivalent is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Fluzone High-Dose Quadrivalent: • Keep it in the refrigerator, store at 2°C to 8°C. Do not freeze.

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

6. Are there any side effects?

Serious side effects can include severe allergic reactions (anaphylaxis) including swelling of the face, lips, tongue, throat or any other part of the body and which may cause difficulty in swallowing or breathing (angioedema). **See your doctor immediately if you notice this.**

Common local side effects include pain, redness, swelling, hardness and bruising at the injection site. Common systemic side effects include muscle aches,

feeling unwell, headache, shivering, nausea and tiredness.

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® High-Dose Quadrivalent

Active ingredient(s): *Inactivated Quadrivalent Influenza Vaccine (Split Virion) Influenza Virus Haemagglutinin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Fluzone High-Dose Quadrivalent. **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 High-Dose Quadrivalent.**

Where to find information in this leaflet:

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

1. Why am I using Fluzone High-Dose Quadrivalent?

Fluzone High-Dose Quadrivalent contains the active ingredient influenza virus haemagglutinin. Fluzone High-Dose Quadrivalent is a vaccine. Vaccines are used to help protect you against infectious diseases.

Fluzone High-Dose Quadrivalent is recommended to help protect you against influenza (flu) and associated pneumonia in persons aged 60 years and older. Influenza (flu) is a disease caused by different strains of the influenza virus. The influenza virus can spread rapidly, especially in homes or institutions, where it can be very easy for someone to catch flu and spread the disease.

Fluzone High-Dose Quadrivalent works by helping the body to make antibodies. These antibodies help the body to recognise the flu virus and help prevent the infection. It takes a few weeks for the body to produce these antibodies.

Fluzone High-Dose Quadrivalent will only help to prevent flu if it is caused by one of the four strains of virus contained in the vaccine or other strains closely related to them. Fluzone High-Dose Quadrivalent will not prevent flu if you are incubating the disease before vaccination or if it is caused by another virus.

Previous injections of flu vaccine are unlikely to give you protection against the current strains of flu virus most common this year, so you will need to receive a vaccine against flu every year especially if you are at risk.

Your doctor will be able to recommend the best time for you to be vaccinated. Flu is present every year, even when epidemics or outbreaks are not reported.

2. What should I know before I am given Fluzone High-Dose Quadrivalent?

Warnings

Do not use Fluzone High-Dose Quadrivalent if:

- you are allergic to the active ingredients, or any of the ingredients listed at the end of this leaflet
- you have ever had a severe allergic reaction after getting any flu vaccine.

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

Check with your doctor if you:

- have or have had Guillain-Barré syndrome (severe muscle weakness) after getting a flu vaccine
- have or have had an immune response problem because the immune response to the vaccine may be diminished
- have bleeding problems or bruise easily

- have an illness with a high or moderate temperature or an acute illness, the vaccination should be postponed until after you have recovered.

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?

3. What if I am taking other medicines?

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Fluzone High-Dose Quadrivalent and affect how it works.

Tell your doctor, nurse or pharmacist if you are taking medicines that may reduce your immune response such as corticosteroids (for example prednisone), medicines used to treat cancer (chemotherapy), radiotherapy or other medicines affecting the immune system.

Having other vaccines

Your doctor will advise you if Fluzone High-Dose Quadrivalent may 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 Fluzone High-Dose Quadrivalent.

4. How is Fluzone High-Dose Quadrivalent given?

Fluzone High-Dose Quadrivalent is administered by your doctor, nurse or pharmacist as a single 0.7 mL injection injected into the muscles of the upper arm.

5. What should I know about being given Fluzone High-Dose Quadrivalent?

Things you should do

Call your doctor straight away if you notice:

- 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.

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 vaccine

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

- Keep Fluzone High-Dose Quadrivalent in the original packaging 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 High-Dose Quadrivalent.

Do not use Fluzone High-Dose Quadrivalent after the expiry date which is stated on the carton after EXP.

Do not use Fluzone High-Dose Quadrivalent if the packaging is torn or shows signs of tampering.

Keep it where young children cannot reach it.

Getting rid of any unwanted vaccine

If you no longer need to use this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this vaccine after the expiry date.

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
At the injection site: • pain • redness (erythema) • swelling, hardness (induration) • bruising • Itching (pruritis) **Systemic side effects:** • muscle aches (myalgia) • feeling unwell (malaise) • headache • fever, chills (shivering) • feeling sick (nausea) • diarrhoea • cough • vertigo • tiredness (fatigue) • vomiting • dizziness • flushing • hives (urticaria) • joint pain (arthralgia) • night sweats	**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
• rash • inflammation of the nose (rhinorrhoea) • pain in extremity • inflammation of the throat (oropharyngeal pain) • abnormal lack of energy (asthenia) • 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
• Severe allergic reactions (anaphylaxis) including swelling of the face, lips, tongue, throat or any other part of the body and which may cause difficulty in swallowing or breathing (angioedema)	**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
• rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson Syndrome) • numbness or pins and needles sensation (paresthesia) • 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 and transverse myelitis, brachial neuritis, Guillain-Barré Syndrome), fits (convulsions including febrile convulsions), facial palsy (Bell's palsy), vision disorders due to the optic nerves dysfunction (optic neuritis/neuropathy),	

Serious side effects	What to do
fainting (syncope) shortly after vaccination • blood vessel inflammation (vasculitis) which may result in skin rashes and in very rare cases in temporary kidney problems, blood vessel opening (vasodilatation) • chest pain • wheezing, throat tightness, difficulty breathing (dyspnoea) • excess of blood in the white of the eye (ocular hyperaemia).	

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 vaccine.

Always make sure you speak to your doctor, nurse or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What Fluzone High-Dose Quadrivalent contains

Active ingredient **(main ingredient)**	Influenza virus haemagglutinin of the following strains • A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238) • A/ Croatia/10136RV/2023 (H3N2)-like strain (A/ Croatia/10136RV/2023, X-425A) • B/ Austria/1359417/2021-like strain (B/ Michigan/01/2021, wild type) • B/Phuket/3073/2013-like strain (B/

	Phuket/3073/2013, wild type)
Other ingredients **(inactive ingredients)**	sodium chloride, dibasic sodium phosphate, monobasic sodium phosphate, octoxinol-9, water for injection, and traces of formaldehyde.
Potential allergens	Fluzone High-Dose Quadrivalent 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 High-Dose Quadrivalent does not contain any antibiotics or preservative.

Fluzone High-Dose Quadrivalent syringes are not made with natural rubber latex.

What Fluzone High-Dose Quadrivalent looks like

Fluzone High-Dose Quadrivalent is supplied as single-dose, 0.7mL pre-filled syringe without needles (Aust R 320962)

Who distributes Fluzone High-Dose Quadrivalent

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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