

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 medicine, speak to your doctor or pharmacist.

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

Fluzone High-Dose Quadrivalent is a vaccine. It 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, 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 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.
- Dose for adults over 60 years: A single 0.7 mL injection

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

5. Are there any side effects?

Common side effects include pain, redness (erythema), swelling, hardness (induration), bruising at the injection site, muscle aches (myalgia), feeling unwell (malaise), headache, shivering, fever, chills (shivering), diarrhoea.

- Serious side effects include severe allergic reactions:
- that may lead to medical emergency with low blood pressure, rapid, shallow breathing, rapid heart rate and weak pulse, cold, clammy skin, and dizziness, that may lead to collapse (shock).
- swelling most apparent in the head and neck, including the face, lips, tongue, throat, or any other part of the body and which may cause difficulty in swallowing or breathing (angioedema).
- a skin condition with severe blisters and bleeding (Stevens-Johnson syndrome)

For more information, including what to do if you have any side effects, see Section [5. Are there any side effects?](#) in the full CMI.

Fluzone High-Dose Quadrivalent®

*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 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 do I need 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. Are there any side effects?](#)
- [6. Product details](#)

1. Why do I need Fluzone High-Dose Quadrivalent?

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. Fluzone High-Dose Quadrivalent may be administered to 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.

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.

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.

You should also note that there are many germs which can cause influenza-like illness. The vaccine will not protect you against these.

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.

How Fluzone High-Dose Quadrivalent works

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. The vaccine will protect you only against the influenza strains contained in the vaccine. It will not protect you from viruses that are unrelated to those contained in the vaccine.

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

Warnings

Do not use Fluzone High-Dose Quadrivalent if:

- if you have ever had a severe allergic reaction to any ingredients of Fluzone High-Dose Quadrivalent listed in the FURTHER INFORMATION section.
- if you have ever had a severe allergic reaction after getting any flu vaccine.
- if you have an illness with a high or moderate temperature or an acute illness, the vaccination should be postponed until after you have recovered.

Take special care with Fluzone High-Dose Quadrivalent:

- **Tell your doctor or pharmacist if you have or have had Guillain-Barré syndrome (severe muscle weakness) after getting a flu vaccine**
- **Tell your doctor or pharmacist if you have or have had an immune response problem because**

the immune response to the vaccine may be diminished

- **Tell your doctor or pharmacist if you have bleeding problems or bruise easily**
- **Tell your doctor or pharmacist if you are pregnant or breast feeding.** Your doctor will discuss the possible risks and benefits of having Fluzone High-Dose Quadrivalent during pregnancy or breastfeeding.

Your doctor should make sure the benefits of vaccination outweigh the risks when recommending Fluzone High-Dose Quadrivalent.

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 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.**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Having other vaccines

- Your doctor will advise you if Fluzone High-Dose Quadrivalent may be given with another vaccine.

4. How is Fluzone High-Dose Quadrivalent given?

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

Dose and Schedule

Adults over 60 years: A single 0.7 mL injection

Method of Administration

Fluzone High-Dose Quadrivalent is injected into the muscles of the upper arm (preferably).

The vaccines should not be injected directly into a blood vessel (intravascularly).

When is it given?

Fluzone High-Dose Quadrivalent should be given annually.

5. Are there any side effects?

Like all medicines, Fluzone High-Dose Quadrivalent can cause side effects, although not everybody gets them.

Less serious side effects

Less serious side effects	What to do
<p>The common local side effects of Fluzone High-Dose Quadrivalent include:</p> <ul style="list-style-type: none"> ● pain, redness (erythema), swelling, hardness (induration), bruising at the injection site <p>Systemic side effects include:</p> <ul style="list-style-type: none"> ● muscle aches (myalgia) ● feeling unwell (malaise) ● headache ● shivering ● fever, chills (shivering) ● diarrhoea 	<p>These side effects usually clear up within a few days. If events continue or become severe, please tell your doctor or pharmacist.</p>
<p>Other side effects not listed above have been reported occasionally with Fluzone High-Dose Quadrivalent and other flu vaccines:</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● injection site itching (pruritis) ● tiredness (fatigue) ● feeling sick (nausea), vomiting, cough, inflammation of the throat (oropharyngeal pain) ● abnormal lack of energy (asthenia), dizziness, flushing, joint pain (arthralgia), night sweats, rash, inflammation of the nose (rhinorrhoea), vertigo, excess of blood in the white of the eye (ocular hyperaemia) ● pain in extremity ● numbness or pins and needles sensation (paraesthesia) ● 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 	

Less serious side effects	What to do
<p>(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), fainting (syncope) shortly after vaccination, lethargy</p> <ul style="list-style-type: none"> ● 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 ● muscle weakness ● indigestion (dyspepsia) ● wheezing, throat tightness, difficulty breathing (dyspnoea) 	

Less serious side effects	What to do
<ul style="list-style-type: none"> 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
<p>See a doctor immediately if you experience severe allergic reactions:</p> <ul style="list-style-type: none"> that may lead to medical emergency with low blood pressure, rapid, shallow breathing, rapid heart rate and weak pulse, cold, clammy skin, and dizziness, that may lead to collapse (shock). swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body 	<p>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.</p>

Serious side effects	What to do
<p>and which may cause difficulty in swallowing or breathing (angioedema).</p> <ul style="list-style-type: none"> • a skin condition with severe blisters and bleeding (Stevens-Johnson syndrome) <p>See a doctor if you experience allergic reactions:</p> <ul style="list-style-type: none"> • allergic reactions such as skin reactions that may spread throughout the body including itching, hives, rash, redness. 	

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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.

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

6. Product details

This medicine is only available with a doctor's prescription.

What Fluzone High-Dose Quadrivalent contains

Active ingredient (main ingredient)	Fluzone High-Dose Quadrivalent contains 4 killed influenza virus strains recommended for the 2019 influenza season: <ul style="list-style-type: none">• A/Michigan/45/2015 (H1N1)pdm09-like virus (A/Michigan/45/2015 X-275)• A/Switzerland/8060/2017 (H3N2)- like virus (A/Brisbane/1/2018 X-311)• B/Phuket/3073/2013-like virus (B/Phuket/3073/2013)• B/Colorado/06/2017-like virus (B/Maryland/15/2016 BX-69A)
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<p>Other ingredients (inactive ingredients)</p>	<p>sodium chloride, dibasic sodium phosphate, monobasic sodium phosphate, octoxinol-9, water for injection, and traces of formaldehyde.</p>
<p>Potential allergens</p>	<p>Fluzone High-Dose Quadrivalent contains less than 1 microgram ovalbumin (egg protein) per dose.</p> <p>Fluzone High-Dose Quadrivalent does not contain any antibiotics or preservative.</p> <p>Fluzone High-Dose Quadrivalent syringes are not made with natural rubber latex.</p>

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

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)

Storing Fluzone High-Dose Quadrivalent

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 out of reach and sight of children.**
- **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 2C to 8C. 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 have Fluzone High-Dose Quadrivalent if the packaging is torn or shows signs of tampering.

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

Who distributes Fluzone High-Dose Quadrivalent

sanofi-aventis australia pty ltd
12 - 24 Talavera Road
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This leaflet was prepared in November 2021.

fluz-hd-qiv-ccds4-cmiv2-19nov21