

## Fluzone High-Dose

Inactivated Trivalent Influenza Vaccine (Split Virion)

### Consumer Medicine Information

#### What is in this leaflet

**Read all of this leaflet carefully before you are vaccinated.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you. Do not pass it on to others.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

- What Fluzone High-Dose is and what it is used for
- Before you are given Fluzone High-Dose
- How Fluzone High-Dose is given
- Possible side effects
- Storing Fluzone High-Dose
- Further information

#### What Fluzone High-Dose is and what it is used for

Fluzone High-Dose is a vaccine. Vaccines are used to help protect you against infectious diseases.

Fluzone High-Dose is recommended to help protect you against influenza. Fluzone High-Dose may be administered to persons aged 65 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 will only help to prevent flu if it is caused by one of the three strains of virus contained in the vaccine, or other strains closely related to them. Fluzone High-Dose 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 works

Fluzone High-Dose 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.

#### Before you are given Fluzone High-Dose

*When you must not be given it*

#### Do not have Fluzone High-Dose:

- If you have ever had a severe allergic reaction to:
  - Eggs or egg products
  - Any of the other ingredients of Fluzone High-Dose listed in the FURTHER INFORMATION section.
- If you have ever had a severe allergic reaction after getting any flu vaccine.
- Before speaking to your doctor, if you have an acute illness with or without high temperature.

#### Take special care with Fluzone High-Dose

- **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 during pregnancy or breastfeeding.

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

#### 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 may be given with another vaccine.

#### How Fluzone High-Dose is given

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

#### Dose and Schedule

Adults over 65 years: A single 0.5 mL injection

#### Method of Administration

Fluzone High-Dose 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 should be given annually

#### Possible side effects

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

The most common local side effects of Fluzone High-Dose include:

- pain, redness (erythema) and swelling, at the injection site

Systemic side effects include:

- muscle aches (myalgia)
- feeling unwell (malaise)
- headache
- fever

**These side effects usually clear up within a few days. If events continue or become severe, please tell your doctor or pharmacist.**

Other side effects not listed above have been reported occasionally with Fluzone High-Dose and other flu vaccines:

- inflammation of nerves leading to weakness, such as weakness of facial muscles (facial palsy), visual disturbances (optic neuritis/neuropathy) or shoulder and arm pain (brachial neuritis)
- fainting (syncope), dizziness, tingling or numbness of hands or feet (paraesthesia)
- Shortness of breath (dyspnoea), sore throat and discomfort when swallowing (pharyngitis), runny or blocked nose and sneezing (rhinitis)
- Vomiting
- temporary inflammation of nerves causing pain, paralysis and sensitivity disorders (Guillain-Barré syndrome [GBS])
- fits (convulsions) with or without fever
- unusual weakness (asthenia) or tiredness (fatigue), pain in extremities or chest pain
- Redness of the eyes (ocular hyperaemia)
- Skin disorders such as Stevens-Johnson syndrome
- severe allergic reaction (anaphylaxis)
- temporary reduction in the number of blood particles called platelets (thrombocytopenia), swollen glands in neck, armpit or groin (lymphadenopathy)

**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.**

#### Storing Fluzone High-Dose

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

- **Keep out of reach and sight of children.**
- **Keep Fluzone High-Dose 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.**

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

**Do not have Fluzone High-Dose 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.

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## Further Information

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### *What Fluzone High-Dose contains*

#### **Ingredients**

Active Ingredients:

Fluzone High-Dose contains 3 killed influenza virus strains recommended for the 2018 influenza season:

- A/Michigan/45/2015 (H1N1)pdm09-like virus (A/Michigan/45/2015 X-275)
- A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus (A/Singapore/INFIMH-16-0019/2016 NIB-104)
- B/Phuket/3073/2013-like virus (B/Phuket/3073/2013; Yamagata lineage)

The other ingredients include sodium chloride, dibasic sodium phosphate, monobasic sodium phosphate, octoxinol-9, water for injection, and traces of formaldehyde.

Fluzone High-Dose contains less than 1 microgram ovalbumin (egg protein) per dose.

Fluzone High-Dose does not contain any antibiotics or preservative.

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

### *What Fluzone High-Dose looks like and contents of the pack*

Fluzone High Dose is supplied as:

- Single-dose, 0.5mL pre-filled syringe (gray plunger rod) without needles.

### *Name and Address of Australian Sponsor*

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### *AUST R number*

AUST R 285932

### *Date of preparation*

12 January 2018

fluzonehd-ccdsV1-cmiv2-12jan18