

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

FLUZONE® High-Dose Quadrivalent

Influenza Virus Vaccine Quadrivalent Types A and B, Zonal Purified, Subvirion

Read this carefully before you start taking **FLUZONE® High-Dose Quadrivalent** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **FLUZONE® High-Dose Quadrivalent**.

What is FLUZONE® High-Dose Quadrivalent used for?

FLUZONE® High-Dose Quadrivalent is a vaccine used to prevent influenza in adults 65 years of age and older to protect against four different types of influenza viruses (two A strains and two B strains) contained in the vaccine.

You cannot catch influenza from this vaccine as the virus has been killed and split into small particles that are not infectious.

The National Advisory Committee on Immunization (NACI) advises yearly influenza vaccination for all Canadians who are able to have the vaccine. For more information about influenza and the vaccine, see the NACI Statement on Seasonal Influenza Vaccines for this year.

(<https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html>)

How does FLUZONE® High-Dose Quadrivalent work?

FLUZONE® High-Dose Quadrivalent causes your body to produce its own protection against four different types of influenza virus (2 A strains and 2 B strains). After you get a flu shot, your immune system produces antibodies against the strains of virus that are in the vaccine. Your body takes up to 4 weeks after vaccination to produce antibodies. The antibodies are effective for the duration of the flu season. When you are exposed to the virus, the antibodies will help to keep you from getting sick. If you do get the flu, you may not be as sick.

FLUZONE® High-Dose Quadrivalent contains four times the amount of killed, split virus particles for each type compared to standard-dose influenza vaccines. The higher dose is intended to give people 65 years and older a better immune response and, therefore, better protection against the flu.

As with all vaccines, FLUZONE® High-Dose Quadrivalent does not protect 100% of people immunized.

What are the ingredients in FLUZONE[®] High-Dose Quadrivalent?

This vaccine complies with the WHO (World Health Organization) recommendation (Northern hemisphere) for the 2023-2024 season.

Medicinal ingredients: Each 0.7 mL dose of FLUZONE[®] High-Dose Quadrivalent contains 60 mcg of killed split viruses from each of the four strains of influenza virus for the 2023-2024 season. The viruses in FLUZONE[®] High-Dose Quadrivalent are:

- A/Victoria/4897/2022 (H1N1)pdm09-like strain
- A/Darwin/9/2021(H3N2) - like strain,
- B/Austria/1359417/2021 - like strain
- B/Phuket/3073/2013 - like strain.

Non-medicinal ingredients: Formaldehyde (trace amounts), egg protein (trace amounts), sodium phosphate-buffered isotonic sodium chloride solution, and Triton[®] X-100.

Does not contain adjuvant, preservative, or antibiotics.

FLUZONE[®] High-Dose Quadrivalent comes in the following dosage forms:

Individual doses in a prefilled syringe.

The packaging of FLUZONE[®] High-Dose Quadrivalent does not contain any latex.

Do not use FLUZONE[®] High-Dose Quadrivalent if:

You have ever had a severe allergic reaction to:

- egg or egg products
- any component of FLUZONE[®] High-Dose Quadrivalent

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FLUZONE[®] High-Dose Quadrivalent. Talk about any health conditions or problems you may have, including if you:

- **Have any diseases of the immune system or are having treatment that affects the immune system.** The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems.
- **Have a bleeding disorder or are taking blood-thinning medications.** Tell the person giving you the injection about your condition. There is a risk of excessive bleeding at the injection site if the vaccine is not given carefully.
- **Have an allergy to egg protein or any component of the vaccine.**
- **Have a fever or serious illness.** Wait until you are better before receiving the flu shot. A person who has a mild illness (such as a mild cold) may have the flu shot. Ask your doctor, nurse or pharmacist for advice.
- **Have a history of Guillain-Barré syndrome (GBS) within 6 weeks after a previous influenza vaccination.**

- **Have fainted with a previous injection.** Fainting can occur after, or even before, any vaccination. Appropriate measures should be taken to prevent falling injury.

Other warnings you should know about:

FLUZONE® High-Dose Quadrivalent will help protect against the strains of flu virus contained in the vaccine or those that are closely related. FLUZONE® High-Dose Quadrivalent will not necessarily protect against any other strains of flu virus.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

FLUZONE® High-Dose Quadrivalent must not be mixed with other vaccines or medicinal products in the same syringe.

How to take FLUZONE® High-Dose Quadrivalent:

Usual dose:

For persons 65 years or older - recommended dose is 0.7 mL.

Inject the vaccine into the deltoid (shoulder) muscle.

Overdose:

If you think you, or a person you are caring for, have taken too much FLUZONE® High-Dose Quadrivalent, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Not Applicable for this vaccine.

What are possible side effects from using FLUZONE® High-Dose Quadrivalent?

These are not all the possible side effects you may have when taking FLUZONE® High-Dose Quadrivalent. If you experience any side effects not listed here, tell your healthcare professional.

The flu vaccine cannot cause influenza because it does not contain any live virus. The most common side effect is pain where you got the injection and muscle pain. There may be others such as headache and malaise (feeling unwell), injection site redness and swelling, and shivering.

Serious side effects and what to do about them		
Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
RARE		
Anaphylaxis difficulty breathing, dizziness, a weak and rapid pulse, skin rash		X
Allergic reaction Rash, itching or hives on the skin, swelling of the face, lips, tongue, or other parts of the body		X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Sanofi Pasteur Limited cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store in a refrigerator at 2° to 8°C. **Do not freeze.** Discard the vaccine if it has been exposed to freezing.

Do not use vaccine after expiration date shown on the label.

Keep out of reach and sight of children.

If you want more information about FLUZONE® High-Dose Quadrivalent:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the Sanofi Canada website (www.sanofi.ca) or by contacting the vaccine producer, Sanofi Pasteur Limited at 1- 888-621-1146.

This leaflet was prepared by Sanofi Pasteur Limited.

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