

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

FLUZONE® Quadrivalent

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

Read this carefully before you start taking FLUZONE® 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® Quadrivalent.

What is FLUZONE® Quadrivalent used for?

FLUZONE® Quadrivalent is a vaccine used to prevent influenza. Influenza (or flu) is an infection caused by the influenza virus.

This vaccine may be given to adults and children 6 months of age and older.

Flu symptoms can include fever, headache, muscle pain, runny nose, sore throat, extreme tiredness and cough. Some people get much sicker.

The influenza virus spreads when a person who has the flu coughs or sneezes into the air. Small droplets of the flu virus stay in the air for a short time then fall onto surfaces nearby. You can get the flu by:

- breathing in these droplets through your nose or mouth.
- the droplets landing directly on your eyes.
- touching the hands of a person who has the flu and then touching your eyes, nose or mouth.
- touching surfaces that have been contaminated with flu virus and then touching your eyes, nose or mouth.

How does FLUZONE® Quadrivalent work?

FLUZONE® Quadrivalent causes your body to produce its own protection against influenza virus. After you get a flu shot, your immune system produces antibodies against the strains of virus that are in the vaccine. 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.

What are the ingredients in FLUZONE® Quadrivalent?

Medicinal ingredients:

This vaccine complies with the WHO (World Health Organization) recommendation (Northern hemisphere) for the 2022-2023 season.

Each 0.5 mL dose of FLUZONE® Quadrivalent contains killed split viruses from four strains of influenza virus for the 2022-2023 season. The viruses in FLUZONE® Quadrivalent are:

- A/Victoria/2570/2019 (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:

Sodium phosphate-buffered, isotonic sodium chloride solution, formaldehyde, and Triton® X-100. The multidose vial contains thimerosal.

FLUZONE® Quadrivalent comes in the following dosage forms:

Individual doses in a vial or a prefilled syringe.

The packaging of FLUZONE® Quadrivalent does not contain any latex.

Do not use FLUZONE® Quadrivalent if:

You have ever had a severe allergic reaction to:

- egg or egg products
- any component of FLUZONE® Quadrivalent

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

- **Diseases of the immune system or who 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.
- **A bleeding disorder or 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 it is not done carefully.
- **Pregnant or breast-feeding women.** It is important that you understand the risks and benefits of vaccination. FLUZONE® should be given to a pregnant or nursing woman only if it is clearly needed. Tell the person giving you the injection if you are pregnant or breast-feeding.
- **Allergy to egg protein or any component of the vaccine.**
- **Fever or serious illness.** Wait until the person is better before giving 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.

- A history of Guillain-Barré syndrome (GBS) within 6 weeks of a previous influenza vaccination.

Other warnings you should know about:

FLUZONE® Quadrivalent will only protect against the strains of flu virus contained in the vaccine or those that are closely related.

FLUZONE® Quadrivalent will not protect against any other strains of flu virus.

The use of FLUZONE® Quadrivalent in infants under 6 months of age is not recommended.

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

Pregnancy Registry

Sanofi Pasteur Inc. is collecting information on pregnancy outcomes and the health of newborns following vaccination with FLUZONE® Quadrivalent during pregnancy. Women who receive Fluzone Quadrivalent during pregnancy are encouraged to contact Sanofi Pasteur Inc. directly or have their healthcare provider contact Sanofi Pasteur Inc. at 1-888-621-1146.

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

The following may interact with FLUZONE® Quadrivalent:

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

How to take FLUZONE® Quadrivalent:

Usual dose:

For children 6 through 35 months - recommended dose is 0.25 mL or 0.5 mL. The National Advisory Committee on Immunization (NACI) recommends that children 6 to through 35 months of age should be given a full dose (0.5 mL).

For persons 3 years or older - recommended dose is 0.5 mL.

Children under 9 years of age who have not received a previous vaccination - 2 doses are required 4 weeks apart. The second dose is not needed if the child received one or more doses of influenza vaccine in a previous season.

For adults and children older than 1 year, inject the vaccine into the deltoid (shoulder) muscle.

For infants and children less than 1 year inject the vaccine into the mid-thigh muscle.

Overdose:

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

Missed Dose:

If a child's second dose is missed, it can be given at any time.

What are possible side effects from using FLUZONE® Quadrivalent?

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

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of FLUZONE® Quadrivalent causing serious harm is extremely small. The small risks associated with FLUZONE® Quadrivalent are much less than the risks associated with getting the disease against which it protects.

The flu vaccine cannot cause influenza because it does not contain any live virus. The most common side effect is soreness where you got the injection. Children and adults might also notice muscle pain and infants may suffer from irritability.

Severe allergic reactions to the flu shots are very rare. A very rare but possible side effect of influenza vaccination is Guillain-Barré syndrome (GBS). This is an autoimmune disease that attacks the nervous system. GBS causes weakness and abnormal sensations. Most patients recover fully. This is not a complete list of side effects. Talk to your doctor or nurse before receiving FLUZONE®.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after having FLUZONE® Quadrivalent. For any unexpected effects after having FLUZONE® Quadrivalent, contact your doctor, nurse or pharmacist.

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/aefi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store in a refrigerator at 2° to 8°C (35° to 46°F). **Do not freeze.** Discard product if it has been exposed to freezing. Protect from light.

Do not use vaccine after expiration date.

Keep out of and sight of children.

A maximum of 10 total doses (0.25 mL dose or 0.5 mL dose) can be withdrawn from the multidose vial.

If you want more information about FLUZONE® 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 manufacturer's website www.sanofi.ca, or by calling 1-888-621-1146. This leaflet was prepared by Sanofi Pasteur Limited.

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