
PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

FLUZONE® High-Dose

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

Read this carefully before you receive FLUZONE® High-Dose and each time you get vaccinated. 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.

What is FLUZONE® High-Dose used for?

FLUZONE® High-Dose is a vaccine used to prevent influenza in adults 65 years of age and older. Influenza (or flu) is an infection caused by the influenza virus.

FLUZONE® High-Dose contains 4 times the amount of antigens compared to the standard dose influenza vaccine, FLUZONE®.

Influenza infection in adults 65 years of age and older is associated with significant morbidity and mortality. Natural and progressive weakening of the immune system over time in older adults (immunosenescence), results in increased susceptibility to influenza-related complications and hospitalization. Also, seniors are less responsive to standard dose influenza vaccine compared to younger adults below 65 years of age.

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® High-Dose work?

FLUZONE® High-Dose 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.

FLUZONE® High-Dose has been shown to induce higher antibody levels and have superior efficacy in preventing laboratory-confirmed influenza (prevented 24% more influenza cases) compared to the standard dose vaccine.

What are the ingredients in FLUZONE® High-Dose?

Medicinal ingredients:

This vaccine complies with the WHO (World Health Organization) recommendation (Northern hemisphere) for the 2025 – 2026 season.

Each 0.5 mL dose of FLUZONE® High-Dose contains split viruses from three inactivated strains of influenza virus for the 2025 – 2026 season. The viruses in FLUZONE® High-Dose are:

- 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)

Non-medicinal ingredients:

Formaldehyde and Triton® X-100.

Does not contain adjuvant, preservative, or antibiotics.

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

Individual doses in a prefilled syringe.

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

Do not use FLUZONE® High-Dose if:

you are allergic to:

- the active substances, or
- any of the other ingredients of this vaccine listed in Section 6, or

any component that may be present in very small amounts such as eggs (ovalbumin, chicken proteins), formaldehyde and octylphenol ethoxylate.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FLUZONE® High-Dose. 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 or bruising easily.** 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 given carefully.
- **An 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.**
- **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 will help protect against the strains of flu virus contained in the vaccine or those that are closely related.

FLUZONE® High-Dose will not necessarily protect against any other strains of flu virus.

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

If, for any reason you have a blood test within a few days following a flu vaccination, please tell your healthcare professional. False results in some types of blood tests have been reported (for example blood tests to detect antibodies against HIV, hepatitis C) in a few patients who had been recently vaccinated.

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® High-Dose:

- FLUZONE® High-Dose must not be mixed with other vaccines or medicinal products in the same syringe.
- If FLUZONE® High-Dose is to be given at the same time as other vaccines, the vaccines should always be administered in different limbs.
- The immunological response may decrease in case of immunosuppressant treatment such as corticosteroids, cytotoxic drugs or radiotherapy.

How to take FLUZONE® High-Dose:

Usual dose:

- For persons 65 years or older - recommended dose is 0.5 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 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?

These are not all the possible side effects you may have when receiving FLUZONE® High-Dose. 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® High-Dose causing serious harm is extremely small. The small risks associated with FLUZONE® High-Dose 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 and muscle pain.

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.

65 years and older population:

Other side effects reported

Very common (may affect more than 1 in 10 people):

- Reactions at the injection site: pain
- Generally feeling unwell (malaise), headache, muscular pain (myalgia)

Common (may affect up to 1 in 10 people):

- Reactions at the injection site: redness (erythema), swelling, hardness (induration), bruising
- Shivering

Uncommon (may affect up to 1 in 100 people):

- Fever
- Injection site itching (pruritis)
- Feeling sick (nausea), diarrhea, dyspepsia, cough
- Abnormal lack of energy (asthenia), lethargy, pruritis, night sweats, rash, muscular weakness

Rare (may affect up to 1 in 1000 people):

- Fatigue

Not known: frequency cannot be estimated from the available data (based on FLUZONE® of TIV HD data)

- Reduction in the number of certain types of particles in the blood called platelets; a low number of these can result in excessive bruising or bleeding (thrombocytopenia), swollen glands in the neck, armpit or groin (lymphadenopathy)
- 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), 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)

- Joint pain (arthralgia)
- Chest pain
- Skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson Syndrome) excess of blood in the white of the eye (ocular hyperemia)
- Inflammation of the throat and the nose: (pharyngitis, rhinitis), wheezing, throat tightness, difficulty breathing (dyspnea)
- Dizziness, vertigo, flushing, hives (urticarial)
- Vomiting

Serious side effects and what to do about them		
Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
Severe allergic reactions 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 difficult in swallowing or breathing (angioedema) Skin condition with severe blisters and bleeding (Stevens-Johnson syndrome)		X
Allergic reactions Skin reactions that may spread throughout the body including itching, hives, rash, redness	X	

Talk to your doctor or nurse before receiving FLUZONE® High-Dose.

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 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-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 product if it has been exposed to freezing. Protect from light. Keep the syringe in the outer carton in order to protect from light.

Do not use vaccine after expiration date.

Keep out of reach and sight of children.

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

- 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 [<https://www.sanofi.com/en/canada/>], or by calling 1-800-265-7927.

This leaflet was prepared by Sanofi.

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