

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Supemtek™

Quadrivalent Recombinant Influenza Vaccine

Read this carefully before you start taking Supemtek and each time you get a dose. 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 Supemtek.

What is Supemtek used for?

Supemtek is a protein-based vaccine used to prevent influenza. This vaccine may be given to adults 18 years and older.

Influenza (or flu) is an infection caused by the influenza virus. Flu symptoms can include fever, headache, muscle pain, runny nose, sore throat, extreme tiredness and cough. Some people, such as children, older adults, and those with chronic medical conditions, can get much sicker. Flu is a disease that can spread rapidly and is caused by different types of strains that can change every year. This is why you might need to be vaccinated every year.

The National Advisory Committee on Immunization (NACI) encourages annual influenza vaccination for all Canadians who are able to have the vaccine, especially for particular groups of people at high risk of influenza-related complications or hospitalization.

How does Supemtek work?

Supemtek causes your body to produce its own natural protection against influenza virus. After you receive the vaccine, your body begins to make substances called antibodies against the strains of virus that are in the vaccine. Antibodies help your body to fight disease and 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. SUPEMTEK™ has been used by many people to lower their risk of catching the flu.

What are the ingredients in Supemtek?

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

Medicinal ingredients:

Each 0.5 mL dose of the vaccine contains 45 mcg haemagglutinin (HA) of purified recombinant protein generated from the genetic sequences from each of the following influenza virus strain types:

A/Wisconsin/588/2019 (H1N1)pdm09 - like strain (A/Wisconsin/588/2019)

A/Darwin/6/2021 (H3N2) - like strain (A/Darwin/6/2021)

B/Austria/1359417/2021 - like strain (B/Austria/1359417/2021)

B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013)

Non-medicinal ingredients: sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate and polysorbate 20.

Supemtek does not contain adjuvant.

Supemtek's production method for recombinant proteins does not use eggs, therefore, there are no egg proteins in the vaccine.

Supemtek does not contain any antibiotics or preservatives. It is latex-free.

There is no gelatin added in Supemtek as a stabilizer.

Supemtek comes in the following dosage forms:

Supemtek is a liquid vaccine that is injected into a muscle. A single dose is 0.5 mL.

Do not use Supemtek if:

- You have a known severe allergy to any ingredient in Supemtek or you have had a severe allergic reaction after receiving a vaccine that contained similar ingredients.

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

- Have a high fever or serious illness. Vaccination may be delayed until your fever is gone.
- Have an allergy to any component of the vaccine.
- You have a poor immune response (immunodeficiency or taking medicines affecting the immune system e.g. medicine against cancer (chemotherapy) or corticosteroid medicines).
- You have a bleeding problem or bruise easily.
- Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if you fainted with a previous injection.

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

How to take Supemtek:

Supemtek is given by a doctor, pharmacist, or nurse as a 0.5 ml injection in the muscle in the upper arm or in the thigh depending on your age and muscle mass.

Usual dose:

A single dose is 0.5 mL.

The vaccination should be given in the muscle, preferably in the deltoid (shoulder) region.

Overdose:

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

Missed Dose:

Not applicable to this vaccine.

What are possible side effects from using Supemtek?

Like all medicines, this vaccine can cause side effects, although not everybody gets them. These are not all the possible side effects you may feel when taking Supemtek. If you experience any side effect not listed here, contact your healthcare professional.

Allergic reactions

Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away if you experience allergic reactions that may be life-threatening.

Serious side effects and what to do about them		
Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
Allergic reactions Symptoms may include difficulty breathing, shortness of breath, swelling of the face, lips, throat or tongue, cold, clammy skin, palpitations, dizziness, weakness, fainting, rash or itching.		✓

The following side effects have been reported with Supemtek:

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

- Local reactions: pain, tenderness
- Fatigue
- Headache
- Muscle pain and joint pain (in adults 18-49 years of age)

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

- Feeling sick (nausea)
- Local reactions: redness, swelling, hardness (induration) around the area where the vaccine is injected
- Fever (> 38°C) (in adults 18-49 years of age)
- Shivering
- Muscle pain and joint pain (in adults 50 years of age and older)

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

- Fever (> 38°C) (in adults 50 years of age and older)

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 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 Supemtek in a refrigerator at 2° to 8°C. **Do not freeze.** Throw the product away if it has been exposed to freezing.

Protect syringes from light.

Do not use after the expiration date.

Keep out of reach and sight of children.

If you want more information about Supemtek:

- 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 (no charge).

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