

Influenza Vaccine (surface antigen, inactivated, adjuvanted with MF59°)

Help prevent influenza with FLUAD®

FLUAD® provides active immunization against influenza disease in adults 65 years of age and older.



Over 160 million doses distributed worldwide!

Visit fluad.ca* for even more information!

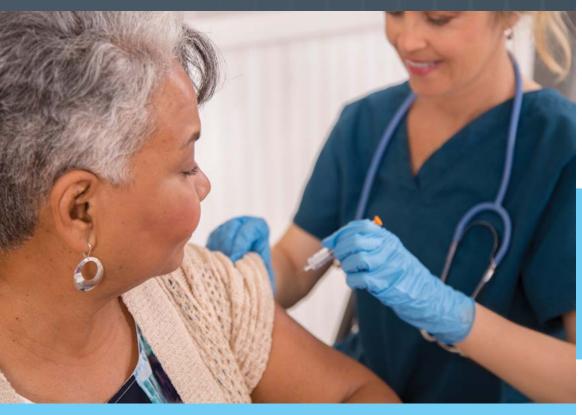
* This link leads to a webpage open to the general public.

Get FLUAD® to help prevent influenza

Read this patient leaflet carefully before you are given **FLUAD**®. Be aware, this leaflet is a summary and will not tell you everything about this vaccine. Contact your doctor or pharmacist if you have any questions.

What is FLUAD® used for?

FLUAD® is an inactivated influenza virus vaccine against influenza subtypes A and B contained in the vaccine, indicated in adults 65 years of age and older.



FLUAD® contains an adjuvant*

How does FLUAD® work?

Like other influenza vaccines, FLUAD® causes the body to produce antibodies against the virus.

• This means that when your body is exposed to the flu virus, the antibodies can help you defend against the attacking virus.

You cannot catch influenza from the vaccine, since it only contains portions of the virus, and not the whole live virus.

Your body takes 2 to 3 weeks to produce antibodies after vaccination.

• Therefore, if you are exposed to influenza immediately before or after your vaccination, you could still develop the illness.

The vaccine will not protect you against the common cold, even though some of the symptoms are similar to influenza.

Influenza viruses change all the time, so different vaccines are made every year. To help stay protected against influenza, you need to be re-vaccinated every year before the winter season.

As with any vaccine, immunization with FLUAD® may not protect 100% of individuals against influenza disease.

It is particularly important for some groups of people to be vaccinated.

These include people with certain medical conditions, elderly people, people who are likely to be exposed to the infection and people on certain medications. If you are in doubt as to whether you should be vaccinated, talk to your local healthcare professionals.



FLUAD® follows the World Health Organization (WHO) and National Advisory Committee on Immunization (NACI) recommendation for vaccination for the northern hemisphere.

^{*}An adjuvant is an ingredient that helps create an enhanced immune response to the vaccine.

Do not use FLUAD® if:

- You have a history of hypersensitivity to egg proteins or other components of the vaccine, or to any of the excipients
- You have had a life-threatening reaction to previous influenza vaccination

If Guillain-Barré Syndrome (GBS) has occurred within six weeks of previous influenza vaccination, the decision to give FLUAD® should be based on careful consideration of the potential benefits and risks.

Immunocompromised patients may have a diminished immune response to FLUAD®.

Other warnings you should know about:

BEFORE you receive FLUAD®, talk to your doctor or pharmacist if you:

- Are allergic to eggs or egg-products
- Are allergic to any of the following: kanamycin and neomycin sulphate, hydrocortisone, formaldehyde, cetyltrimethylammonium bromide, or polysorbate 80
- Have a fever, or you think you may be getting a fever
- Had a serious reaction to any flu vaccine in the past
- Have any known allergies
- Have experienced any health problems
- Are pregnant: ask your doctor for advice
- Are currently on any medication (i.e., immunosuppressant, theophylline, anticoagulants such as warfarin)



FLUAD® does not contain thimerosal or any other preservative. The syringe plunger does not contain latex and FLUAD® is considered safe for use in persons with latex allergies.

Please see the Patient Information Leaflet for a complete list of ingredients.



FLUAD® may be given at the same time as other vaccines.

Immunosuppressive therapies may reduce immune response to FLUAD®.

USE IN SPECIFIC POPULATIONS

- Safety and effectiveness of FLUAD® has not been established in pregnant women and nursing mothers.
- Antibody responses were lower in the geriatric population than in younger adult subjects.

No interaction between FLUAD® and other vaccines or medication is known.

- Immunization with other vaccines should be carried out on separate limbs. It should be noted that the systemic adverse reactions may be intensified.
- The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.
- Although a possible interaction has been suggested in the literature between influenza vaccination and the use of warfarin and theophylline, clinical studies have not shown any adverse effects attributable to these drugs in people receiving influenza vaccine. There were no studies designed to evaluate the drug interactions with FLUAD®.

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

How to take FLUAD®:

FLUAD® is only to be given by injection into a muscle administered by a healthcare professional.

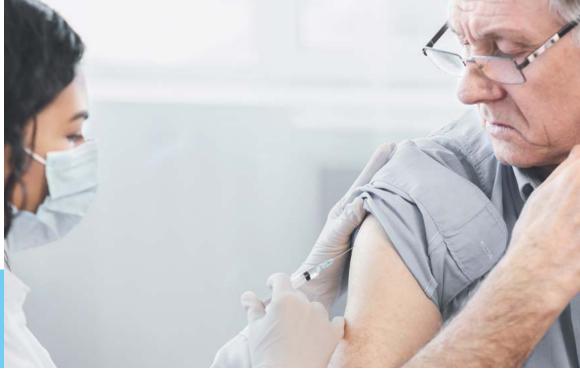
Usual dose:

• Adults aged 65 years and over: A single dose of 0.5 mL.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following administration of the vaccine.

If you think you have taken too much FLUAD®, contact a healthcare professional, hospital emergency department or regional poison control center immediately, even if there are no symptoms.





What are possible side effects from using FLUAD®?

Occasionally people have side effects with influenza vaccines.

The most common of these are:

Fever

Feeling unwell

Shivering

Tiredness

- Headache
- Sweating
- Muscle joint pain
- Warmth

Skin reactions include redness, swelling, pain, ecchymosis (blue/black staining of the skin) and a hardening of the skin at the injection site and itching. These reactions will normally disappear without treatment in a day or two.

In clinical studies for FLUAD® in elderly population, the most common (≥10%) adverse reactions reported were headache, muscle pain, and fatigue as well as local pain, thickening, swelling, and redness at injection site.

Reporting suspected side effects

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 CSL Seqirus cannot provide medical advice.

If you want more information about FLUAD®:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals including the 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.cslseqirus.ca), or by calling 1-855-358-8966.
- Visit fluad.ca*.

The Drug Identification Number (DIN) for **FLUAD**® is 02362384. Provide this DIN to your private insurance company to learn if they cover FLUAD®.



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NOTES		



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