

FLUCELVAX® QUAD

Influenza Vaccine (surface antigen,
inactivated, prepared in cell cultures)



PATIENT INFORMATION



FLUCELVAX® QUAD IS INDICATED TO BE USED IN ADULTS AND CHILDREN 6 MONTHS AND OLDER TO PREVENT INFLUENZA.

NACI
Recommendation

NACI recommends cell-culture based inactivated influenza vaccines, among other influenza vaccines, for adult and children aged 6 months to less than 65 years.²

Visit the consumer site flucelvax.ca for more information!

READ THIS INFORMATION CAREFULLY BEFORE YOU ARE GIVEN FLUCELVAX® QUAD.

This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional and see if **FLUCELVAX® QUAD** is right for you.



WHAT IS **FLUCELVAX®** **QUAD** USED FOR?

FLUCELVAX® QUAD is used in adults and children aged 6 months and older to help prevent influenza.

Influenza, often called “the flu”, is caused by infection with specific influenza viruses. New types of influenza viruses can appear each year. FLUCELVAX® QUAD vaccine contains fragments of four different types of influenza virus. Each year the World Health Organization decides which strains of viruses are most suitable to include in the vaccine.

You cannot catch influenza from the vaccine, as the virus in the vaccine has been killed and split into small non-infectious particles.

The National Advisory Committee on Immunization (NACI) encourages annual influenza vaccination for all Canadians who are able to have the vaccine.

Vaccination against influenza is recommended every year, for anyone wanting to lower their chance of catching influenza. FLUCELVAX® QUAD has been used by many people to lower their risk of catching the flu.

HOW DOES FLUCELVAX[®] QUAD WORK?

FLUCELVAX[®] QUAD vaccine works by helping your body protect itself against infection by the types of influenza viruses that are in the vaccine. The vaccine stimulates the body to make substances called antibodies. Antibodies fight the influenza virus. If you have been vaccinated, when you come into contact with the influenza viruses in the vaccine, your body is usually able to quickly destroy the virus, which may prevent you from getting influenza.

Your body takes a few weeks after vaccination to fully develop effective protection against the influenza virus.

Protection against influenza generally requires one dose of FLUCELVAX[®] QUAD vaccine. Some people including children less than 9 years of age who have not received influenza vaccination before may require two doses.

As with all vaccines, 100% protection cannot be guaranteed.

**FLUCELVAX[®] QUAD is not made using eggs;
there are no egg proteins in the vaccine.**

**The syringe and vial components do not contain latex.
FLUCELVAX[®] QUAD is considered safe for use in persons
with latex allergies.**

**FLUCELVAX[®] QUAD pre-filled syringes contain no preservative
or antibiotics. FLUCELVAX[®] QUAD multi-dose vial formulation
contains a preservative, but does not contain any antibiotics.**



GUIDELINE RECOMMENDATIONS



NACI

The National Advisory Committee on Immunization (NACI) recommends cell-culture based inactivated influenza vaccines, among other influenza vaccines, for adult and children aged 6 months to less than 65 years.²



CPS

The Canadian Paediatric Society (CPS) encourages annual influenza vaccination for all children and youth 6 months of age or older.³



SOGC & NACI

The Society of Obstetricians and Gynecologists of Canada (SOGC) recommends that **all pregnant individuals, at any stage in pregnancy, or individuals who might be pregnant in the upcoming influenza season**, should be offered an inactivated influenza vaccine.⁴

The NACI also strongly recommends that cell-culture based inactivated influenza vaccines, among other influenza vaccines, should be offered to pregnant individuals at any stage of pregnancy.⁵

[†] To help avoid side effects and ensure proper use, talk to your healthcare professional if you are pregnant. Your healthcare professional will be able to discuss the potential risks and benefits of having FLUCELVAX[®] QUAD while you are pregnant. The safety of FLUCELVAX[®] QUAD in pregnancy has not been assessed in randomized clinical trials.

DO NOT USE FLUCELVAX[®] QUAD IF:

- Your child is under 6 months of age. FLUCELVAX[®] QUAD vaccine is approved for use in children aged 6 months and older.
- You or your child have or have had an allergy to FLUCELVAX[®] QUAD or any ingredient listed in this leaflet.

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

- **Have or have had a reaction to vaccination with any of the following:**
 - severe allergic reaction
 - difficulty breathing
 - swelling of the throat
 - syncope
 - fainting or collapse
 - fits or convulsions
 - high temperature (greater than 38.5°C)
 - severe skin reaction at the injection site, including severe bruising
- **Have an infection or temperature higher than 38.5°C**
Your doctor may decide to delay vaccination until the illness has passed. A minor illness such as a cold is not usually a reason to delay vaccination.
- **Have low immunity due to treatment with certain medicines**
- **Have or have had Guillain-Barré Syndrome (GBS)**
An illness which affects the nervous system and causes paralysis.
- **Have allergies to other medicines or substances**
- **Are pregnant or breastfeeding**
Your healthcare professional will be able to discuss the potential risks and benefits of having FLUCELVAX[®] QUAD while you are pregnant or breastfeeding.
- **Have experienced fainting, or feeling faint, with a previous injection**
Fainting can occur following, or even before, any vaccination. Appropriate measures should be taken to prevent injury from falling.

TELL YOUR HEALTHCARE PROFESSIONAL ABOUT ALL THE MEDICINES YOU TAKE, INCLUDING ANY DRUGS, VITAMINS, MINERALS, NATURAL SUPPLEMENTS OR ALTERNATIVE MEDICINES.

HOW FLUCELVAX® QUAD IS GIVEN:

FLUCELVAX® QUAD is given as an injection into a muscle, usually in the upper arm.

USUAL DOSE:

FLUCELVAX® QUAD is given once every year as follows:

- Adults and children 9 years and over: one injection of 0.5 mL.

For children 6 months to less than 9 years old who are receiving influenza vaccine for the first time, it is recommended that a follow-up (booster) dose of FLUCELVAX® QUAD is given 4 weeks after the first dose.

If the follow-up dose is missed, talk to your healthcare professional and arrange another visit as soon as possible.

OVERDOSE:

IF YOU THINK YOU HAVE BEEN GIVEN TOO MANY DOSES OF FLUCELVAX® QUAD OR HAVE BEEN GIVEN IT BY MISTAKE, CONTACT YOUR HEALTHCARE PROFESSIONAL, HOSPITAL EMERGENCY DEPARTMENT OR REGIONAL POISON CONTROL CENTRE IMMEDIATELY, EVEN IF THERE ARE NO SYMPTOMS.

WHAT ARE POSSIBLE SIDE EFFECTS FROM USING FLUCELVAX® QUAD?

These are not all the possible side effects you may experience when taking FLUCELVAX® QUAD. If you experience any side effects not listed here, contact your healthcare professional.

The following are common or very common side effects of FLUCELVAX® QUAD. Most of these side effects are mild and do not last long. Tell your doctor if you or your child have side effects that bother you:

- Injection-site pain, reddening, hardening or swelling
- Headache
- Muscle or joint pain
- Tiredness
- Nausea, vomiting, diarrhea
- Loss of appetite
- Bruising
- Shivering



Younger children (less than 6 years of age) may experience the following common or very common side effects:

- Injection site tenderness
- Irritability
- Sleepiness
- Change of eating habits
- Fever

If you experience any of the rare **serious side effects** mentioned below, **talk to your healthcare professional:**

- **Anaphylaxis:** Difficulty breathing, dizziness, a weak and rapid pulse, skin rash.
- **Allergic reaction:** Rash, itching or hives on the skin, swelling of the face, lips, tongue, or other parts of the body.

IF YOU HAVE A TROUBLESOME SYMPTOM OR SIDE EFFECT THAT IS NOT LISTED HERE OR BECOMES BAD ENOUGH TO INTERFERE WITH YOUR DAILY ACTIVITIES, TALK TO YOUR HEALTHCARE PROFESSIONAL.

REPORTING SUSPECTED SIDE EFFECTS

Should you experience a side effect following immunization, please report it to your doctor, nurse, or pharmacist.

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



If you want more information about **FLUCELVAX® QUAD**:

- 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, the manufacturer's website (www.cslseqirus.ca), or by calling 1-855-358-8966.
- **Visit flucelvax.ca**



The Drug Identification Number (DIN) for **FLUCELVAX® QUAD** is 02494248. Your insurance company may ask for this number.

To report a suspected adverse reaction please contact:

Email: ae.reporting@seqirus.com

Phone: 855-358-8966

Please select option 1 when prompted

References:

1. FLUCELVAX® QUAD Product Monograph.
2. National Advisory Committee on Immunization. Statement on Seasonal Influenza Vaccine for 2024–2025. 2023.
3. Canadian Paediatric Society. Vaccine recommendations for children and youth for the 2023/2024 influenza season.
4. SOGC Clinical Practice Guideline. No.357-Immunization in Pregnancy. 2018.
5. National Advisory Committee on Immunization. Updated Guidance on Influenza Vaccination During Pregnancy. 2023.
6. Data on file.
7. Data on file.



FLUCELVAX® QUAD 

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FREQUENTLY ASKED QUESTIONS

Are cell-culture based inactivated influenza vaccines recommended by NACI as a vaccine option?

NACI Recommendation

Yes. The National Advisory Committee on Immunization (NACI) recommends cell-culture based inactivated influenza vaccine among other flu vaccines, for adults and children aged 6 months to less than 65 years.²

Is FLUCELVAX® QUAD only for patients with egg allergies?

No. FLUCELVAX® QUAD can be used all eligible patients aged 6+ months.¹

Is flu vaccination recommended for children 6 months or older?

Yes. In fact, the Canadian Paediatric Society (CPS) encourages annual flu vaccination for all children and youth 6 months of age or older to help prevent the flu.⁴

Is flu vaccination recommended for pregnant individuals?

Yes. In fact, the Society of Obstetricians and Gynecologists of Canada (SOGC) recommends that all pregnant women, at any stage in pregnancy, or women who might be pregnant in the upcoming influenza season, should be offered an inactivated influenza vaccine to help prevent the flu.⁵



Is FLUCELVAX® QUAD newly available in Canada?

No. FLUCELVAX® QUAD has been available in Canada since:¹

- 2019 for adults and children 9+ years
- 2021 for children 2+ years
- 2022 for children 6+ months

What is the experience of FLUCELVAX® QUAD worldwide?

Over 250 million doses of FLUCELVAX® QUAD have been distributed worldwide.^{6,7}

What are possible side effects from using FLUCELVAX® QUAD?

The most common, or very common, side effects are injection-site pain, reddening, hardening, and swelling, as well as headache, muscle or joint pain, tiredness, nausea, vomiting, diarrhea, loss of appetite, bruising, and shivering. Younger children may experience injection site tenderness, irritability, sleepiness, change of eating habits, and fever. Most of these side effects are mild and do not last long. Tell your doctor if you or your child have side effects that bother you, including ones not listed here.¹

† To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FLUCELVAX® QUAD. Your healthcare professional will be able to discuss the potential risks and benefits of having FLUCELVAX® QUAD. The safety of FLUCELVAX® QUAD in pregnancy has not been assessed in randomized clinical trials.

CSL Seqirus

CSL Seqirus Canada
Kirkland, Québec
www.CSLseqirus.ca
1.844.392.8582
514.221.4877

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