

Flucelvax® Quad

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

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about **Flucelvax® Quad**.

It does not contain all the available information.

It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you having **Flucelvax® Quad** against the benefits they expect it will have for you or your child.

If you have any concerns about Flucelvax® Quad, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What Flucelvax® Quad is used for

Flucelvax® Quad is a vaccine used to help prevent certain types of influenza or “flu”. It is recommended for people aged 9 years of age and older.

Influenza is a sudden respiratory infection caused by a virus. It is usually spread from one person to another by small droplets from coughs and sneezes. The virus enters the nose or throat and may spread to the lungs. It is very contagious. There are several kinds of influenza viruses however they all produce similar illness. Influenza is characterised by a sudden onset of headache, generalised aches and pain, fever that may be followed by a sore throat, a cough and a runny nose.

The severity and types of symptoms can vary. Most people recover in about a week; however, infection with influenza in some people can lead to serious illness, especially those who are “run down” or are in poor health.

Vaccination against influenza helps prevent infection with influenza and to control the spread of the disease.

How it works

Flucelvax® Quad works by causing your body to produce its own protection against the four types of influenza virus from which it is made. It does this by making substances called antibodies in the blood that fight the influenza virus. If a vaccinated person comes into contact with the influenza virus, the body is usually ready to destroy it.

Your body usually takes 2 – 3 weeks after vaccination to develop protection against influenza.

As influenza viruses can change from year to year, **Flucelvax® Quad** may be changed to contain fragments of the new types of virus. Therefore vaccination is required yearly.

Please note that an influenza vaccine may only protect you against the types of influenza virus from which it is made. It will not protect you from other types of influenza virus or from infections with other agents causing flu-like symptoms (such as the common cold).

Most people will produce enough antibodies against the influenza virus. However, as with all vaccines, 100% protection cannot be guaranteed.

The virus in the vaccine has been killed. Therefore the vaccine cannot give you or your child “the flu”.

Before you or your child are given Flucelvax® Quad

When you or your child must not be given Flucelvax® Quad

Do not have Flucelvax® Quad if you or your child has previously had a severe allergy to:

- any of the ingredients listed at the end of this leaflet
- any influenza vaccine.

Symptoms of a severe allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives.

Do not have Flucelvax® Quad if you or your child have a high temperature or sudden illness.

A minor illness such as a cold should not be a problem but talk to your doctor about this if being vaccinated.

Do not have Flucelvax® Quad if your child is under 9 years old.

Flucelvax® Quad is not recommended for use in persons under 9 years.

Do not have Flucelvax® Quad after the expiry date printed on the pack.

Do not have Flucelvax® Quad if the packaging is torn or shows signs of tampering.

If you are not sure whether you or your child should have Flucelvax® Quad, talk to your doctor, nurse or pharmacist.

Before you or your child are given Flucelvax® Quad

Tell your doctor if you or your child have reacted to previous vaccination with any of the following:

- severe allergic reaction (anaphylaxis)
- difficulty breathing
- swelling of the throat
- fainting or collapse
- shock-like state or being unresponsive for a long period of time
- fits or convulsions
- temperature (greater than 38°C) or high temperature (greater than 39°C)
- severe skin reaction at the injection site, including severe bruising

Tell your doctor if you or your child have an infection or high temperature.

Your doctor may decide to delay vaccination until the illness has passed. A mild illness, such as a cold, is not usually a reason to delay vaccination.

Tell your doctor if you or your child have, or have had, any medical conditions, especially the following:

- Guillain-Barre Syndrome (an inflammatory illness affecting nerves resulting in weakness of muscles)
- lowered immunity due to diseases such as some blood disorders, malaria, kidney

disease requiring dialysis, HIV/AIDS or cancer

- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)

Tell your doctor if you or your child have allergies to:

- any other medicines
- any other substances, such as latex, foods, preservatives or dyes

Tell your doctor if you are pregnant, or are planning to become pregnant.

Your doctor will discuss the potential risks and benefits of having **Flucelvax® Quad** vaccine during pregnancy, and advise on the timing of **Flucelvax® Quad** vaccination with regards to pregnancy.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the potential risks and benefits of having **Flucelvax® Quad** vaccine while you are breast-feeding.

Taking other medicines

Tell your doctor or pharmacist if you or your child are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and **Flucelvax® Quad** may interfere with each other. These include:

- immunoglobulins, blood products used to prevent some infections
- medicines which lower the immune system, such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy).

Your doctor will consider whether an adjustment of medication is necessary.

Having other vaccines

Tell your doctor if you or your child have had any vaccines in the last 4 weeks.

Your doctor will decide if Flucelvax® Quad may be given with another vaccine.

Your doctor and pharmacist may have more information on medicines and vaccines to be careful with or to avoid during vaccination with **Flucelvax® Quad**.

How Flucelvax® Quad is given

Flucelvax® Quad is given as an injection, usually into your upper arm muscle by a doctor or nurse.

How much is given

Flucelvax® Quad vaccine is given once every year, as follows:

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

When it is given

Flucelvax® Quad vaccine is usually given before the start of the influenza season or when recommended by your doctor or nurse. Vaccination for influenza should be repeated every year as new types of influenza virus can appear each year.

After having Flucelvax® Quad

Things you or your child must do

Keep an updated record of you and your child's vaccinations.

Keep any follow-up appointments with your doctor or clinic.

Have any blood tests when your doctor says to.

Your doctor may wish to test your body's response to **Flucelvax® Quad** to make sure that you have developed protection against influenza.

Things to be careful of

Be careful driving or operating machinery until you know how Flucelvax® Quad affects you.

Flucelvax® Quad should not normally interfere with your ability to drive or operate machinery. However, it may cause tiredness in some people.

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well after having Flucelvax® Quad.

Flucelvax® Quad may have unwanted side effects in a few people. All medicines, including vaccines, can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment if you get some of the side effects.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you or your child notice any of the following and they worry you:

These are the more common side effects of **Flucelvax® Quad**. Mostly these are mild and short lived.

- local reaction around the injection site such as pain, redness, swelling or the formation of hard lumps and bruising
- muscle aches or joint pain (not caused by exercise)
- flu-like symptoms, such as headache, tiredness, fever, sore throat, runny nose, blocked nose, sneezing, cough, chills
- nausea, vomiting, diarrhoea
- loss of appetite

Tell your doctor immediately if you or your child notice any of the following:

These may be serious side effects. You or your child may need urgent medical attention. These serious side effects are rare.

- tingling of the hands or feet, or sudden numbness or weakness in the legs or arms
- extensive swelling of the injected limb
- generalised skin reactions including itching, bumps on the skin or non-specific rash

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, (anaphylaxis)
- shortness of breath, wheezing or trouble breathing
- feeling weak or paralysed, or generally feeling sore or tender

- rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting (shock)

These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.

Very rarely, a serious disorder called Guillain-Barré syndrome (GBS) may occur. GBS is an autoimmune syndrome caused by your body's own immune system. GBS may make you feel weak; you may have difficulty moving around or you may experience numbness and tingling in your limbs.

All of these side effects are rare.

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist if you notice anything that is making you or your child feel unwell.

Do not be alarmed by this list of possible side effects.

You or your child may not experience any of them.

Storing Flucelvax® Quad

Flucelvax® Quad is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store

Flucelvax® Quad:

- **Keep it where children cannot reach it.**
- **Keep Flucelvax® Quad in the original pack until it is time for it to be given.**
- **Keep it in the refrigerator, between 2°C and 8°C. Do not freeze Flucelvax® Quad. Discard if the vaccine has been frozen.**
Freezing destroys the vaccine

Product description

What it looks like

Flucelvax® Quad is a clear to slightly milky-white liquid in a pre-filled syringe.

Ingredients

- Active ingredients:
Each 0.5 mL contains 15 micrograms of influenza virus fragments (influenza virus haemagglutinins) from each of the following types of influenza virus:
 - A/ Wisconsin/588/2019 (H1N1)pdm09 - like strain
 - A/ Hong Kong/45/2019 (H3N2) – like strain
 - B/ Washington/02/2019 - like strain
 - B/ Phuket/3073/2013 – like strainThese strains have been recommended by the Australian Influenza Vaccine Committee for the 2021 Southern Hemisphere season.
- Other ingredients:
Sodium chloride, Potassium chloride, Magnesium chloride hexahydrate, Dibasic sodium phosphate dihydrate, Dibasic potassium phosphate, Water for injections.

Flucelvax® Quad may also contain traces of beta-propiolactone, cetyltrimethylammonium bromide, and polysorbate 80, as residues of the manufacturing process.

Flucelvax® Quad does not contain lactose, gluten, tartrazine, any other azo dyes, antibiotics or preservative.

Manufacturer/Distributor/ Supplier

Flucelvax® Quad sponsored by:

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AUSTRALIA
AUST R 319093
AUST R 341450

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