

Fluad®

Inactivated Influenza Vaccine, Adjuvanted

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fluad®.

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 Fluad® against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What Fluad® is used for

Fluad® is a vaccine used to help prevent certain types of influenza or “flu”. It is recommended for people aged 65 years and over.

It is especially beneficial in people aged 65 and over with cardiovascular disease, respiratory disease or diabetes and those who are considered to have an increased risk of complications from influenza.

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 the elderly and 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

Fluad® works by causing your body to produce its own protection against the three types of influenza virus it is made from. 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, Fluad® may be changed to contain fragments of the new types of virus. Therefore vaccination is required yearly.

Please note that an influenza vaccine will only protect you against the types of influenza virus used to make it. 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 influenza. However, as with all

vaccines, 100% protection cannot be guaranteed.

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

Before you are given Fluad®

When you must not be given it

Do not have Fluad® if you have an allergy to:

- Fluad® or any of the ingredients listed at the end of this leaflet
- any other influenza vaccines
- eggs and/or chicken proteins

Symptoms of an 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 Fluad® if you 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 Fluad® if you are pregnant or breastfeeding.

Fluad® is not recommended for use during pregnancy.

Do not have Fluad® if you are under 65.

Fluad® is not recommended for use in persons under 65 years.

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

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

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

Before you are given Fluad®

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

- life-threatening 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
- high temperature (greater than 40°C)
- severe skin reaction at the injection site, including severe bruising

Tell your doctor if you 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 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)
- bleeding problems

Tell your doctor if you have allergies to:

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

Taking other medicines

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

Some medicines and Fluad® may interfere with each other. These include:

- medicines used to control epilepsy or convulsions such as phenytoin, carbamazepine and phenobarbitone
- theophylline, a medicine used to control asthma
- warfarin, a medicine used to prevent blood clots
- 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).

These medicines may be affected by Fluad®. Your doctor will consider whether adjustment of your medication is necessary.

Having other vaccines

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

Fluad® 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 Fluad®.

How Fluad® is given

Fluad® is given as an injection, usually into your shoulder muscle by a doctor or nurse.

How much is given

A single 0.5 mL dose.

When it is given

Fluad 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 Fluad®

Things you must do

Keep an updated record of your 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 Fluad® 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 Fludad® affects you. Fludad® should not normally interfere with your ability to drive or operate machinery. However, it may cause dizziness, light-headedness or tiredness in some people.

Side effects

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

Fludad® 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 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 notice any of the following and they worry you:

- local reaction around the injection site such as redness, itchiness, tenderness, pain or discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars
- flushing or redness of the skin
- headaches
- tiredness, weakness or fatigue
- generally feeling unwell
- fever
- chills/increased sweating
- soreness, aching muscles, muscle tenderness or weakness (not caused by exercise)
- nausea

These are the more common side effects of Fludad®. Mostly these are mild and usually disappear within 1-2 days without treatment.

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

- abscess at the injection site
- unusual bleeding, bruising or purple spots on the skin
- skin rash, itchy spots or red lumps on the skin
- painful, swollen joints
- earache or temporary hearing loss
- severe dizziness, unsteadiness when walking or spinning sensation or vertigo
- sore throat, difficulty swallowing
- fast heart beat
- tingling of the hands or feet, or sudden numbness or weakness in the legs or arms

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

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)
- pinkish, itchy swellings on the skin, also called hives or nettle rash (urticaria)
- shortness of breath, wheezing or trouble breathing
- fits or convulsions

- feeling weak or paralysed, or generally feeling sore or tender
- passing little or no urine, which may be associated with nausea, loss of appetite and weakness
- rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting (shock)
- headache and high temperature associated with hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, stiff neck and sensitivity to light

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

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 feel unwell.

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

You may not experience any of them.

Storing Fludad®

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

- **Keep it where children cannot reach it.**
- **Keep Fludad® 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 Fludad®.** Freezing destroys the vaccine

Product description

What it looks like

Fludad® is a 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/Michigan/45/2015 (H1N1) pdm09 - like strain
 - A/Singapore/INFIMH-16-0019/2016 (H3N2) – like strain
 - B/Phuket/3073/2013 - like strainThese strains have been recommended by the World Health Organisation (WHO) for the 2018 Southern Hemisphere winter.
- **Other ingredients/Adjuvant: MF59C.1:** containing squalene, polysorbate 80, sorbitan trioleate, sodium citrate dihydrate, citric acid monohydrate, water for injection.
Other: sodium chloride, potassium chloride, potassium phosphate monobasic, sodium phosphate dibasic, magnesium chloride hexahydrate, calcium chloride dihydrate, water for injection.

Fludad® may also contain traces of kanamycin sulfate, neomycin sulfate, formaldehyde, chicken proteins, cetyltrimethylammonium bromide (CTAB), sucrose, and barium sulphate as residues of the manufacturing process.

Fludad® does not contain lactose, gluten, tartrazine or any other azo dyes.

Manufacturer/Distributor/Supplier

Fludad® sponsored by:
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