

Patient Information Leaflet on

Fluarix[®] (Influenza) 2007/2008 Vaccine

This leaflet tells you about influenza (flu) vaccine. Please read it carefully. If there is anything you do not understand, please ask your doctor, nurse or pharmacist (chemist). Please keep this leaflet. You may want to read it again.

What is in Fluarix?

The name of your vaccine is Fluarix. It is an inactivated (killed) influenza (flu) virus vaccine in a suspension for injection. Each 0.5 ml dose of the vaccine contains 15 micrograms of highly purified sub-units (haemagglutinin) of A/Solomon Islands/3/2006 (H₁N₁)-like strain, A/Wisconsin/67/2005 (H₃N₂)-like strain and B/Malaysia/2506/2004-like strain. These are the flu viruses that are likely to cause flu this winter. It is supplied in a prefilled syringe.

This vaccine also contains inactive ingredients. These are sodium chloride, disodium phosphate dodecahydrate, potassium dihydrogen phosphate, potassium chloride, magnesium chloride hexahydrate, RRR- α -tocopheryl hydrogen succinate, polysorbate 80, octoxinol 10 and Water for Injections.

The vaccine is available in packs of one and 10 prefilled syringes.

Who makes Fluarix Vaccine?

The Product Licence holder is SmithKline Beecham plc, trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

The vaccine is manufactured by SSW Dresden, Branch of SmithKline Beecham Pharma GmbH & Co. KG, Zirkusstrasse 40, 01069, Dresden, Germany.

What is Fluarix and how does it work?

The vaccine contains killed influenza virus strains. When you are given the vaccine your body will make antibodies (your body's natural defence system) against the influenza virus strains. This will protect you against influenza infection.

This vaccine is used for immunisation against influenza in adults and children over six months of age.

Before having this vaccine

If you answer "Yes" to any of the following questions, tell your doctor or nurse. You may not be able to have the vaccine or it may have to be delayed.

If you are the parent of a child who is to be vaccinated you should check that none of the following applies to your child.

- Do you have a fever or an infection?
- Have you any known allergies?
- Do you think you may be allergic to Fluarix, or any of the ingredients listed, or formaldehyde, gentamicin sulphate or sodium deoxycholate?
- In addition, this vaccine contains small amounts of thiomersal leftover from the manufacturing process, which could also cause an allergic reaction.
- Have you ever had a severe allergic reaction to eggs or chicken protein?
- Do you have any illness which may affect your immune system?
- Are you receiving medicines (such as steroid tablets) which may affect your immune system?
- Do you have any bleeding disorders, such as haemophilia, because you may get bleeding at the injection site?
- Are you pregnant or do you think you may be?
- Have you experienced any health problems after previous administration of a vaccine?

Having the vaccine

Fluarix Vaccine is injected, into muscle or under the skin, usually in the upper arm. For adults and children over three years of age a 0.5 ml dose is given. For children aged six months to 35 months either a 0.5 ml or 0.25 ml dose is given. Children who have not been previously vaccinated against influenza should receive a second dose of vaccine after a minimum four-week interval.

The injection should protect against influenza viruses which are likely to cause flu this winter. The viruses which cause flu change from year to year, so it is important to have a new flu vaccine to cover these different strains of virus. Your doctor will advise you on when you should receive your next injection.

After having the vaccine

What unwanted effects might you have?

At the site of the injection you may have pain, redness, swelling, bruising or hardness. You may feel unwell and have a fever, shivering, sweating, tiredness, headache and aches in your muscles and joints. These effects should only last a day or two.

You should tell your doctor if you get any of the following unwanted effects: nerve pain (neuralgia), numbness / pins and needles (possibly with fever), convulsions, unexplained or easy bruising, skin rash, urinary symptoms.

Some people can have an allergic reaction to the vaccine. You may be asked to stay in the surgery or vaccination area for a short time after the vaccination to check that you do not have an immediate allergic reaction. Tell the doctor or nurse if you get a rash, have tightness in the throat or shortness of breath or any other unwanted effects.

Storage of this vaccine

This vaccine should be stored in a refrigerator between 2°C and 8°C, but not frozen. Store in the original package in order to protect from light. The doctor or nurse will check that the expiry date on the label has not passed.

Disease information on influenza

Influenza (flu) is a highly infectious illness caused by a virus. It is passed on by breathing in droplets of air from infected people. The main signs of the illness include fever, chills, headache, a dry cough, a sore throat and aches and pains in the muscles. Although many people recover, usually within a few days, the illness can be serious in older people or people with other illnesses such as diabetes, lung, kidney and heart disease.

The influenza vaccine is especially useful for older people or those at more risk of infection due to other illnesses. It is also helpful for preventing the spread of influenza in places such as nursing homes and old people's homes where a rapid spread of the illness is more likely.

Fluarix will only prevent disease caused by influenza viruses. Infection with other agents causing flu-like symptoms are not preventable by the vaccine.

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