

FLUARIX[®]

(Inactivated Split Influenza Vaccine)

CONSUMER MEDICINE INFORMATION LEAFLET

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about FLUARIX vaccine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the possible risks of you/your child having FLUARIX against the expected benefits.

If you have any concerns about receiving FLUARIX talk to your doctor, nurse or pharmacist.

Keep this leaflet with this vaccine. You may need to read it again.

WHAT FLUARIX IS USED FOR

FLUARIX is used to prevent certain types of influenza. The vaccine works by causing the body to produce its own protection (antibodies) against three different types of influenza virus. Each year new types of influenza virus can appear, so every year FLUARIX is changed to contain fragments of the new types of virus. Therefore, influenza vaccination is recommended every year.

Please note that FLUARIX will only protect you against the three types of influenza virus used to make the vaccine. It will not protect you from influenza caused by other types of influenza virus or from infections with other agents causing flu-like symptoms (such as the common cold).

Influenza is an infectious illness. Influenza is spread by small droplets from the nose, throat or mouth of an infected person. Symptoms of influenza begin 48 hours after coming into contact with the virus. These consist of chills, fever, generalised aches and pains, headache and respiratory symptoms (sore throat, runny nose, cough). The severity and type of symptoms can vary. Most people recover completely within a week. The risk of serious complications (eg. pneumonia and death) is greater in very young, very old and chronically ill persons.

FLUARIX can be used in adults and children older than 6 months of age. Annual vaccination against influenza is especially recommended for the following groups:

- Persons over 65 years of age
- Persons who suffer from chronic diseases, especially:
 - heart diseases.
 - Lung or respiratory disease. This includes asthma requiring regular preventative treatment, cystic fibrosis, and other chronic lung diseases with impaired lung function.
 - Other chronic illnesses such as: diabetes, kidney problems, poor immunity (including people with HIV) or abnormal haemoglobin (for example sickle cell disease),
 - Chronic neurological conditions such as

multiple sclerosis and seizures.

- Women who are planning to become pregnant and those who will be 4-9 months pregnant during the flu season.
- people living in nursing homes, hostels or other long-term care facilities,
- Staff of nursing homes and other chronic care facilities may also be vaccinated in an attempt to protect the patients.
- people who have contact with anyone from the groups of people listed above.
- People involved in the poultry industry during confirmed avian flu activity.
- people in the workforce, especially those in the essential services
- travellers

FLUARIX may also be prescribed for certain other persons. **Please talk to your doctor if you have any questions.**

BEFORE RECEIVING FLUARIX

DO NOT HAVE FLUARIX IF :

- you/your child have had an allergic reaction to FLUARIX, or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

If you/your child have had FLUARIX before and became unwell, tell your doctor, nurse

or pharmacist before the next dose is given.

- you/your child have had an allergic reaction or became unwell after any other influenza vaccine (Fluvax or Vaxigrip).
- you/your child are allergic to egg proteins such as in eggs or feathers
- you/your child are allergic to gentamicin.
- you/your child have a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before being vaccinated.
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

If you are not sure whether you/your child should have FLUARIX, talk to your doctor or nurse. Do not give this vaccine to anyone else; your doctor has prescribed it specifically for you/your child.

BEFORE HAVING FLUARIX TELL YOUR DOCTOR IF:

- you are or think you may be pregnant or if you intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of receiving FLUARIX during pregnancy.
- you are breast feeding. Your doctor will discuss the risks and benefits of vaccination, however the vaccine is not expected to cause problems for breast-fed babies.
- you/your child have had or have Guillain-Barre Syndrome (an inflammatory illness

affecting nerves resulting in weakness of muscles)

- you/your child have any medical conditions, such as
 - an immune deficiency condition
 - or a bleeding disorder
- you/your child have allergies to any medicines or substances, such as dyes, foods or preservatives.
- you/your child have received another vaccine, or are taking any prescription (eg theophylline, phenytoin, phenobarbitone, carbamazepine or warfarin) or OTC (over-the-counter) medicines. In particular mention if you/your child are taking medicines which suppress the immune system, such as steroids or cyclosporin.

Some vaccines may be affected by other vaccines or medicines. Your doctor or pharmacist will be able to tell you what to do if FLUARIX is to be given with another vaccine or medicine.

Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if you or your child fainted with a previous injection.

HOW FLUARIX IS GIVEN

The doctor or nurse will give FLUARIX as an injection. **If you have any concerns about how this vaccine is to be given, talk to your doctor, nurse or pharmacist.**

HOW MUCH IS GIVEN

For adults and children over 3 years of age: 0.5mL is given.
For children aged 6 months to 3 years: 0.25mL is given.

HOW IT IS GIVEN

FLUARIX is generally injected into the upper leg muscle in infants under 12 months of age. In children over 12 months of age and older children and adults the injection may be given in the upper arm muscle. For some people with bleeding problems, the dose may need to be given under the skin (subcutaneously).

FLUARIX should never be given intravenously.

WHEN IT IS GIVEN

For adults and older children FLUARIX is generally given as a single dose each year during Autumn.

For children aged from 6 months to 9 years, who are receiving influenza vaccination for the first time, a second dose should be given 4 weeks after the first dose. However, one dose is sufficient for such children who have been previously vaccinated against influenza.

- First dose: on an elected date
- Second dose: 4 weeks after the first (ONLY for children aged 6 months to 9 years receiving influenza vaccination for the first time)

IF A DOSE IS MISSED

If a scheduled dose is missed, talk to your doctor or nurse and arrange another visit as soon as possible.

AFTER RECEIVING FLUARIX

THINGS TO BE CAREFUL OF:

Be careful driving or operating machinery until you know how FLUARIX affects you. FLUARIX should not normally interfere with your ability to drive a car or operate machinery. But in some people vaccination can cause dizziness or lightheadedness. Make sure you know how you react to FLUARIX before you

drive a car or operate machinery, or do anything that could be dangerous if you are dizzy or lightheaded.

SIDE EFFECTS

Tell your doctor, nurse or pharmacist as soon as possible if you/your child does not feel well during or after having had a dose of FLUARIX.

FLUARIX helps protect most people from influenza, but it may have unwanted side effects in a few people. All medicines and vaccines can have side effects. Sometimes they are serious; most of the time they are not. Some side effects may need medical treatment.

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

Most unwanted effects with FLUARIX are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site.

MILD EVENTS

Tell your doctor if you notice any of the following that are troublesome or ongoing:

- ◆ redness, swelling, a hard lump, soreness, bruising or itching around the injection site
- ◆ fever, chills, shivering, sweating, dizziness, headache, malaise (generally unwell)
- ◆ muscle aches and pains
- ◆ joint pain
- ◆ loss of appetite
- ◆ irritability
- ◆ drowsiness

MORE SERIOUS EFFECTS THAT MAY OCCUR RARELY

As with all vaccines given by injection there is a very small risk of serious allergic reaction. Contact your doctor immediately or go to the casualty department of your nearest hospital if any of the following happens:

- ◆ swelling of limbs, face, eyes, inside of nose, mouth or throat
- ◆ shortness of breath, breathing or swallowing difficulties
- ◆ hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions
- ◆ unusual tiredness or weakness that is sudden and severe

As with all vaccines given by injection there is a very small risk of such reactions. Allergy to FLUARIX is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

Other events reported after influenza vaccination include:

- ◆ rare reports of serious neurological disorders. However, these events have not been definitely linked to the use of influenza vaccines
- ◆ Guillain-Barre Syndrome (an inflammatory illness affecting nerves resulting in weakness of muscles).
- ◆ transient swollen glands in the neck, armpit or groin
- ◆ painful swelling in the arms or legs
- ◆ inflammation of the brain and spinal cord

- ◆ pain associated with touch, heat and cold
- ◆ vomiting
- ◆ Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- ◆ itching, rash
- ◆ blood vessels inflammation which may result in skin rashes and in very rare cases in temporary kidney problems

Other events not listed above, can also occur during or soon after a dose of vaccine. **Check with your doctor if you notice any other effects.**

STORAGE

FLUARIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store FLUARIX always:

- Keep FLUARIX in the refrigerator stored between +2°C and +8°C.

THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.

- Keep the vaccine out of the reach of children.
- Keep FLUARIX in the original pack until it is time for it to be given.

Ask your pharmacist what to do with any left over FLUARIX that has expired or has not been used.

PRODUCT DESCRIPTION

WHAT IT LOOKS LIKE

FLUARIX comes in a prefilled syringe. It is a colourless, slightly opalescent liquid.

INGREDIENTS

Each 0.5mL dose of FLUARIX contains 15 micrograms of each of the three types of influenza virus fragments.

- A/California/7/2009 (H1N1) like strain
- A/Perth/16/2009 (H3N2) like strain
- B/Brisbane/60/2008 like strain

The vaccine also contains polysorbate 80, octoxinol 10, sodium deoxycholate, sodium chloride, magnesium chloride, potassium chloride, potassium phosphate monobasic, sodium phosphate dibasic dodecahydrate, sucrose, alpha tocopheryl acid succinate and traces of formaldehyde and gentamicin sulfate.

FLUARIX is not made with any human blood or blood products, or any other substances of human origin.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

FURTHER INFORMATION

FLUARIX is only available if prescribed by a doctor.

FLUARIX comes as prefilled syringes in packs of 1 and 10

MANUFACTURER

GlaxoSmithKline Biologicals
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Zirkusstrasse 40
01069 Dresden Germany

FLUARIX is supplied in New Zealand by:

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