FLUARIX®

Inactivated Split Influenza Vaccine

Consumer Medicine Information

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 or 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 the vaccine. You may need to read it again.

What FLUARIX is used for

FLUARIX is used to help 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).

FLUARIX cannot give you or your child influenza because the viruses in the vaccine have been killed.

Influenza is an infectious illness and is spread by small droplets from the nose, throat or mouth of an infected person. The most common symptoms of influenza include fever, sore throat, runny nose, coughing, general aches and pains, headache, weakness and tiredness. 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.

Please talk to your doctor if you have any questions.

Before you are given FLUARIX

When you or your child must not be given FLUARIX

FLUARIX must not be given if you or your child:

- have had an allergic reaction to FLUARIX, or any of the ingredients listed at the end of this leaflet.
- have had an allergic reaction or became unwell after any other influenza vaccine (e.g. Fluvax or Vaxigrip etc).
- are allergic to egg proteins such as in eggs or feathers.
- are allergic to gentamicin.
- have a severe infection with a high temperature. Your doctor may decide to delay vaccination until the illness has passed. A minor infection such as a cold is not usually a reason to delay vaccination, but talk to your doctor or nurse about this before being vaccinated.

Some of the 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
- rash, itching or hives on the skin

FLUARIX should not be given after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you or 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 or your child.

Your doctor will discuss with you the possible risks and benefits of receiving FLUARIX.

Before being given 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 or your child have had or have Guillain-Barré Syndrome (an inflammatory illness affecting nerves resulting in weakness of muscles).
- you or your child have any medical conditions, such as:
  - an immune deficiency condition, or
  - a bleeding disorder.
- you or your child have allergies to any medicines or substances, such as dyes, foods or preservatives.
- you or your child have received another vaccine, or are taking any prescription (e.g. theophylline, phenytoin, phenobarbitone, carbamazepine or warfarin) or OTC (over-the-counter) medicines. In particular mention if you or your child are taking medicines which suppress the immune system, such as steroids or cyclosporin.
- you or your child are allergic to latex. The removable rubber needle shield of the prefilled syringe with an attached needle contains natural rubber latex.

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: 0.5 mL is given.

For children aged 6 months to 3 years: 0.25 mL 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 before the start of the influenza season 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)

Vaccination should be repeated every year as new types of influenza virus can appear each year.

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 being given 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 light-headedness. 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 light-headed.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you or your child do 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.

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)
- vomiting, diarrhoea, stomach pain

- muscle aches and pains
- joint pain
- loss of appetite
- irritability
- drowsiness

The above list includes mild side effects.

Tell your doctor as soon as possible if you notice any of the following:

- transient swollen glands in the neck, armpit or groin
- painful swelling in the arms or legs
- Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- inflammation of the brain and spinal cord, inflammatory illness affecting nerves resulting in weakness of muscles

In very young children high fevers may result in convulsions (fits). It is advisable to monitor young children for high fevers post (influenza) vaccination.

There have been rare reports of Guillain-Barré Syndrome (an inflammatory illness affecting nerves resulting in weakness of muscles), however these events have not been definitely linked to the use of influenza vaccines.

The above list includes serious side effects that may require medical attention.

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

Allergy to FLUARIX is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell during or after a dose of vaccine.

Other events not listed above, can also occur during or soon after a dose of vaccine.

How to store FLUARIX

Storage

FLUARIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. 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 sight and 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 in packs of 1 or 10. It is a colourless, slightly opalescent liquid.

Ingredients

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

- A/California/7/2009-like virus
- A/Hong Kong/4801/2014 (H3N2)-like virus
- B/Brisbane/60/2008-like virus

The vaccine also contains:

- polysorbate 80
- octoxinol 10
- sodium chloride
- magnesium chloride
- potassium chloride
- potassium phosphate monobasic
- sodium phosphate dibasic dodecahydrate
- alpha tocopheryl acid succinate
- water for injections
- ovalbumin (≤0.05 micrograms)
- formaldehyde (≤5 micrograms)
- hydrocortisone (trace)
- gentamicin sulfate (trace)
- sodium deoxycholate (trace)

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.

FLUARIX is only available if prescribed by a doctor.

Supplier

GlaxoSmithKline NZ Limited
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Fluarix is a registered trade mark of the GSK group of companies.

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