FLUARIX TETRA

Inactivated Split Influenza Vaccine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about FLUARIX TETRA 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 TETRA against the expected benefits.

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

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

What Fluarix Tetra is used for

FLUARIX TETRA is used to help prevent certain types of influenza. The vaccine works by causing the body to produce its own protection (antibodies) against four different types of influenza virus.

The types of influenza antigen contained in FLUARIX TETRA may change from one year to another. Each year, the Australian Influenza Vaccine Committee (AIVC) recommends which ones to include. This decision is based on the types of influenza virus thought most likely to occur during the next flu season. Therefore, influenza vaccination is recommended every year.

Please note that FLUARIX TETRA will only protect you against the four 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 TETRA 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 (e.g. pneumonia and death) is greater in very young, very old and chronically ill persons. FLUARIX TETRA can be used in adults and children older than 3 years of age.

Before you are given FLUARIX TETRA

When you or your child must not be given FLUARIX TETRA

FLUARIX TETRA must not be given if you or your child:

- have had an allergic reaction to FLUARIX TETRA 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, Vaxigrip etc)

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 TETRA 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 TETRA, 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 TETRA.

Before being given FLUARIX TETRA

Tell your doctor if:

- you or your child 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.
- 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 TETRA 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 latex, dyes, foods or preservatives.
- you or 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 or 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 TETRA 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 TETRA is given

The doctor or nurse will give FLUARIX TETRA 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.

How it is given

FLUARIX TETRA is generally injected into the upper arm or upper thigh muscle.

When it is given

For adults and older children FLUARIX TETRA is generally given as a single dose each year before the start of the influenza season, which is usually in winter.

- First dose: on an elected date
- Second dose: 4 weeks after the first (ONLY for children aged 3 years 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 you miss a dose

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

After being given FLUARIX TETRA

Things to be careful of:

Be careful driving or operating machinery until you know how FLUARIX TETRA affects you. FLUARIX TETRA 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 TETRA 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 or your child do not feel well during or after having had a dose of FLUARIX TETRA.

FLUARIX TETRA 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 TETRA 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)
- muscle aches and pains
- joint pain
- loss of appetite, feeling sick, vomiting, diarrhoea, stomach pain
- 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
- vomiting
- Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- 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 TETRA 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 side effects not listed above may also occur in some people.

After being given FLUARIX TETRA

Storage

FLUARIX TETRA is usually stored at the doctor's clinic or surgery, or at the pharmacy.

If you need to store FLUARIX TETRA always:

- Keep FLUARIX TETRA 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 TETRA in the original pack until it is time for it to be given.

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

Product description

What it looks like

FLUARIX TETRA comes in a pre-filled syringe in packs of 1 and 10. It is a colourless, slightly opalescent liquid.

Ingredients

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

- A/Michigan/45/2015 (H1N1)pdm09-like virus
- A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus
- B/Phuket/3073/2013-like virus
- B/Brisbane/60/2008-like virus

The vaccine also contains:

- polysorbate 80
- octoxinol 10
- α-tocopheryl hydrogen succinate
- sodium chloride
- disodium phosphate dodecahydrate
- potassium dihydrogen phosphate
- potassium chloride
- magnesium chloride hexahydrate
- water for injections
- ovalbumin (≤0.05 micrograms)
- formaldehyde (≤5 micrograms)
- hydrocortisone (trace)
- gentamicin sulfate (trace)
- sodium deoxycholate (trace)

FLUARIX TETRA 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.

Manufacturer/ Distributor/ Supplier

FLUARIX TETRA is manufactured by:

GlaxoSmithKline Biologicals
Branch of SmithKline Beecham Pharma GmbH & Co KG
Zirkusstrasse 40
01069 Dresden Germany

FLUARIX TETRA is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
Level 4,
436 Johnston Street,
Abbotsford, Victoria, 3067

Registration Numbers:

AUST R 200674 - prefilled syringe without needle*

AUST R 210806 - prefilled syringe with needle*

AUST R 242512 – prefilled syringe with detached needle

*not currently supplied

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16 October 2017

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