Reason for Update: Type II variation – Annual Flu Strain Update
Market: IE
Agency Approval Date:
Text Date: 17 April 2020
Text Issue and Draft No.: Issue 05 Draft 01

Package leaflet: Information for the user

Fluarix Tetra suspension for injection in pre-filled syringe
Influenza vaccine (split virion, inactivated)

Read all of this leaflet carefully before you or your child start receiving this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you or your child get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

This leaflet has been written assuming the person receiving the vaccine is reading it, but it can be given to adolescents and children so you may be reading it for your child.

What is in this leaflet

1. What Fluarix Tetra is and what it is used for

Fluarix Tetra is a vaccine. This vaccine helps to protect you against influenza (flu), particularly in subjects who run a high risk of associated complications. The use of Fluarix Tetra should be based on official recommendations.

When a person is given the vaccine Fluarix Tetra, the immune system (the body's natural defence system) will produce its own protection (antibodies) against the disease. None of the ingredients in the vaccine can cause flu.

Flu is a disease that can spread rapidly and is caused by different types of strains that can change every year. Therefore, this is why you might need to be vaccinated every year. The greatest risk of catching flu is during the cold months between October and March. If you were not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you run the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated. Fluarix Tetra will protect you against the four strains (two A virus subtypes and two B types contained in the vaccine) from about 2 to 3 weeks after the injection.

The incubation period for flu is a few days, so if you are exposed to flu immediately before or after your vaccination, you could still develop the illness.

The vaccine will not protect you against the common cold, even though some of the symptoms are similar to flu.

2. What you need to know before you use Fluarix Tetra

To make sure that Fluarix Tetra is suitable for you, it is important to tell your doctor or pharmacist if any of the points below apply to you. If there is anything you do not understand, ask your doctor or pharmacist to explain.

Do not use Fluarix Tetra
- If you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6) or any components that may be present in very small amounts such as eggs (ovalbumin or chicken proteins), formaldehyde, gentamicin sulphate or sodium deoxycholate.
- If you have an illness with a high temperature or acute infection, the vaccination shall be postponed until after you have recovered.

Warnings and precautions
Talk to your doctor or pharmacist before you receive Fluarix Tetra:

- if you have a poor immune response (immunodeficiency or taking medicines affecting the immune system).

- if, for any reason, you have a blood test within a few days following a flu vaccination. This is because false positive blood test results have been observed in a few patients who had recently been vaccinated.

- if you have a bleeding problem or bruises easily.

Your doctor will decide if you should receive the vaccine.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection, therefore tell the doctor or nurse if you fainted with a previous injection.

As with all vaccines, Fluarix Tetra may not fully protect all persons who are vaccinated.

Other medicines and Fluarix Tetra

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Fluarix Tetra can be given at the same time as other vaccines by using separate limbs.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Your doctor/pharmacist will be able to decide if you should receive Fluarix Tetra. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Fluarix Tetra has no or negligible influence on the ability to drive or use machines.

Fluarix Tetra contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free".

Fluarix Tetra contains potassium

This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially "potassium-free".

3. How Fluarix Tetra is given

Dosage

Adults receive one 0.5 ml dose.

Use in children:
Children from 6 months and older receive one 0.5 ml dose.
If your child is younger than 9 years of age and has not been previously vaccinated against flu, a second dose should be given after at least 4 weeks.

Method and/or route of administration

Your doctor will administer the recommended dose of the vaccine as an injection into the muscle.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

During clinical trials, the following side effects have been observed.

Side effects that occurred in children 6 to 36 months of age

Very common (these may occur with more than 1 in 10 doses of the vaccine):
- Loss of appetite
- Irritability
- Drowsiness
- Pain at the injection site
- Redness at the injection site

Common (these may occur with up to 1 in 10 doses of the vaccine):
- Fever
- Swelling at the injection site

Side effects that occurred in children 3 to 6 years of age

Very common (these may occur with more than 1 in 10 doses of the vaccine):
- Pain at the injection site
- Redness at the injection site
- Swelling at the injection site
- Irritability

Common (these may occur with up to 1 in 10 doses of the vaccine):
- Loss of appetite
- Drowsiness
- Fever

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):
- Rash
- Itching at the injection site

Side effects that occurred in children 6 to 18 years of age

Very common (these may occur with more than 1 in 10 doses of the vaccine):
- Aching muscles
- Pain at the injection site
- Redness at the injection site
- Swelling at the injection site
- Fatigue

Common (these may occur with up to 1 in 10 doses of the vaccine):
- Feeling sick, diarrhoea, vomiting, stomach pain
- Headache
- Joint pain
- Shivering
- Fever

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):
- Rash
- Itching at the injection site

Side effects that occurred in adults ≥18 years of age

Very common (these may occur with more than 1 in 10 doses of the vaccine):
- Local reactions: pain
- Fatigue
- Muscular pain (myalgia)

Common (these may occur with up to 1 in 10 doses of the vaccine):
- Headache
- Feeling sick, diarrhoea, vomiting, stomach pain
- Joint pain (arthralgia)

- Fever, shivering
- Local reactions: redness, swelling

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):
- Bruising (hematoma), itching (pruritus) around the area where the vaccine is injected
- Dizziness

In addition, side effects that occurred during clinical studies in subjects from 3 years of age with Fluarix (trivalent influenza vaccine) were:

Common (these may occur with up to 1 in 10 doses of the vaccine):
- Hardness (induration) around the area where the vaccine is injected
- Sweating

These reactions usually disappear within 1-2 days without treatment.

Next to the above side effects, the following side effects occurred occasionally during general use of Fluarix and/or Fluarix Tetra:

- allergic reactions:
  - leading to medical emergency with a failure of the circulatory system to maintain adequate blood flow to the different organs (shock) in rare cases,
  - swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body (angioedema) in very rare cases.
- skin reactions that may spread throughout the body including itchiness (pruritus, urticaria) and redness (erythema) of the skin
- neurological disorders that may result in stiff neck, confusion, numbness, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all the body (encephalomyelitis, neuritis, Guillain-Barré syndrome)
- temporary swelling of the glands in the neck, armpit or groin (transient lymphadenopathy)
- flu-like symptoms, generally feeling unwell (malaise)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fluarix Tetra

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Do not freeze.

Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fluarix Tetra contains

The active substance is: Influenza virus (inactivated, split) of the following strains*:
A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09 - like strain (A/Guangdong-Maonan/SWL1536/2019, CNIC-1909) 15 micrograms HA**
A/Hong Kong/2671/2019 (H3N2) - like strain (A/Hong Kong/2671/2019, NIB-121) 15 micrograms HA**
B/Washington/02/2019 - like strain (B/Washington/02/2019, wild type) 15 micrograms HA**
B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, wild type) 15 micrograms HA**

per 0.5 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin

This vaccine complies with the World Health Organization (WHO) recommendation (northern hemisphere) and EU recommendation for the **2020/2021** season.

The other ingredients are: sodium chloride, disodium phosphate dodecahydrate, potassium dihydrogen phosphate, potassium chloride, magnesium chloride hexahydrate, α-tocopheryl hydrogen succinate, polysorbate 80, octoxinol 10 and water for injections.

What Fluarix Tetra looks like and contents of the pack

Fluarix Tetra is a suspension for injection in pre-filled syringe (0.5 ml) with or without needles in the following pack sizes:

- with 1 needle: pack sizes of 1 or 10
- with 2 needles: pack size of 1
- without needle: pack sizes of 1 or 10.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

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Manufacturer:
GlaxoSmithKline Biologicals, Branch of SmithKline Beecham Pharma GmbH & Co. KG, Zirkusstrasse 40, D-01069, Dresden, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Member State	**Name**
Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Spain, Slovakia, Slovenia, Sweden, UK	Fluarix Tetra
Belgium, Luxembourg	α-RIX-Tetra
France	FluarixTetra
Germany	Influsplit Tetra

This leaflet was last revised in 04/2020.

The following information is intended for healthcare professional only:

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

Immunisation should be carried out by intramuscular injection.

Fluarix Tetra should under no circumstances be administered intravascularly.

Fluarix Tetra may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs.

The vaccine should be allowed to reach room temperature before use.

Shake before use. Inspect visually prior to administration.

Instructions for administration of the vaccine presented in pre-filled syringe

To attach the needle to the syringe, refer to the drawing.

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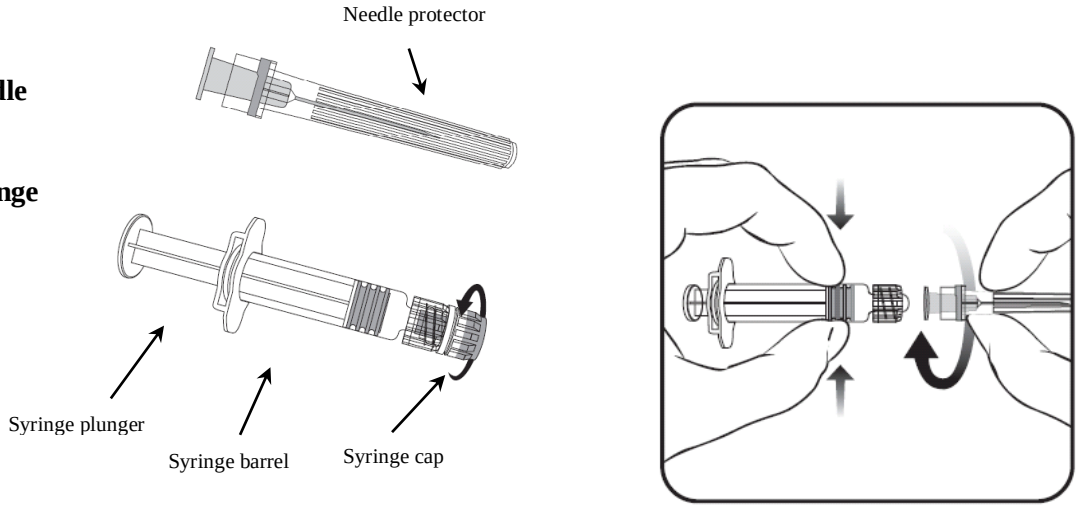

1. Holding the syringe <u>barrel</u> in one hand (avoid holding the syringe plunger), unscrew the syringe cap by twisting it anticlockwise.
2. To attach the needle to the syringe, twist the needle clockwise into the syringe until you feel it lock (see picture).
3. Remove the needle protector, which on occasion can be a little stiff.
4. Administer the vaccine.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.