PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a physician's prescription only

Fluarix Tetra

Suspension for injection in pre-filled syringe

Inactivated influenza vaccine

Each dose (0.5 ml) contains:

Four influenza strains:

A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238)
15 micrograms
A/Thailand/8/2022 (H3N2)-like strain (A/Thailand/8/2022, IVR-237)
15 micrograms
B/Austria/1359417/2021-like strain (B/Austria/1359417/2021, BVR-26)
15 micrograms
B/Phuket/3073/2013-like strain (B/Phuket/3073/2013, wild type)
15 micrograms

For the list of inactive and allergenic ingredients in the preparation, see section 2: "Important information about some of the ingredients of the medicine" and section 6: "Additional information".

Read this leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Fluarix Tetra is an active immunisation of adults and children from 6 months of age for the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus subtypes contained in the vaccine.
The use of Fluarix Tetra is based on official recommendations.
When a person is given the Fluarix Tetra vaccine, the immune system (the body's natural defense system) will produce its own protection (antibodies) against the disease. None of the ingredients of 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 there is risk of catching flu until then. The physician will be able to recommend to you the best time to be vaccinated. Fluarix Tetra will protect you against four strains contained in the vaccine, starting 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 may still develop the illness.
The vaccine will not protect you against the common cold, even though some of the symptoms are similar to flu symptoms.

2. BEFORE USING THE MEDICINE

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

Do not use Fluarix Tetra if:
- you are sensitive (allergic) to the active ingredients or any of the additional ingredients contained in the medicine (see details in section 6 "Additional information") or any ingredients that may be present in very small amounts, such as eggs (ovalbumin or chicken proteins), formaldehyde, gentamicin sulphate or sodium deoxycholate.
- you have an illness with a high temperature or acute infection, the vaccination should be postponed until after you have recovered.

Special warnings regarding use of the medicine
Before the treatment with Fluarix Tetra, tell the physician:
- if you have a poor immune response (immunodeficiency or taking medicines affecting the immune system).
- if, for any reason, you plan to have a blood test 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 bruise easily.

The physician will decide if you can receive the vaccine.
Fainting may occur (mostly in adolescents) following, or even before, any needle injection; therefore, tell the physician or nurse if you fainted following a previous injection.
Like other vaccines, Fluarix Tetra may not fully protect all patients who were vaccinated.

Drug Interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.
Fluarix Tetra can be given at the same time as other vaccines by injecting into separate limbs.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your physician or pharmacist for advice before taking this medicine. The physician/pharmacist will decide if you should receive Fluarix Tetra.
As a rule of thumb, ask your physician or pharmacist for advice before taking medicines during pregnancy and when breastfeeding.

Driving and operating machinery
Fluarix Tetra does not affect or has a negligible effect on the ability to drive and operate machinery.

Important information about some of the ingredients of the medicine
The preparation contains less than 1 mmol (23 mg) sodium per dose, i.e., it is considered essentially a "sodium-free" preparation.
The preparation contains less than 1 mmol (39 mg) potassium per dose, i.e., it is considered essentially a "potassium-free" preparation.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the physician only. The usual dosage is generally:
Adults receive one 0.5 ml dose.

Use in children:
Children from 6 months of age 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 have passed.

A healthcare professional will inject the recommended dosage of the vaccine into the muscle.

Do not exceed the recommended dose.
Adhere to the treatment regimen as recommended by the physician.
Do not take medicines in the dark! Check the label and dose <u>each time</u> you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Fluarix Tetra may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

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

<u>Side effects that occurred in children from 6 to 36 months of age</u>
Very common side effects (occur with more than 1 in every 10 doses of the vaccine):
loss of appetite, irritability, drowsiness, pain and/or redness at the injection site.

Common side effects (occur with up to 1 in every 10 doses of the vaccine):
fever, swelling at the injection site.

<u>Side effects that occurred in children from 3 to 6 years of age</u>
Very common side effects (occur with more than 1 in every 10 doses of the vaccine):
pain and/or redness and/or swelling at the injection site, irritability.

Common side effects (occur with up to 1 in every 10 doses of the vaccine):
loss of appetite, drowsiness, fever.

Uncommon side effects (occur with up to 1 in every 100 doses of the vaccine):
rash, itching at the injection site.

<u>Side effects that occurred in children from 6 to 18 years of age</u>
Very common side effects (occur with more than 1 in every 10 doses of the vaccine):
aching muscles, pain and/or redness and/or swelling at the injection site, fatigue.

Common side effects (occur with up to 1 in every 10 doses of the vaccine):
nausea, diarrhoea, vomiting, stomach pain, headache, joint pain, shivering, fever.

Uncommon side effects (occur with up to 1 in every 100 doses of the vaccine):
rash, itching at the injection site.

<u>Side effects that occurred in adults from ages 18 and up</u>
Very common side effects (occur with more than 1 in every 10 doses of the vaccine):
pain at the injection site, fatigue, muscular pain (myalgia).

Common side effects (occur with up to 1 in every 10 doses of the vaccine):
headache, nausea, diarrhoea, vomiting, stomach pain, joint pain (arthralgia), fever, shivering, redness and/or swelling at the injection site.

Uncommon side effects (occur with up to 1 in every 100 doses of the vaccine):
bruising (haematoma), itching (pruritus) around the injection site, dizziness.

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

Common side effects (occur with up to 1 in every 10 doses of the vaccine):
hardness (induration) around the injection site, sweating.
These effects usually disappear within 1-2 days without treatment.

In addition to the side effects listed above, the following side effects occurred during general use of Fluarix and/or Fluarix Tetra.

Rare side effects (occur with up to 1 in every 1,000 doses of the vaccine):
- allergic reactions:
  - reactions that lead to a medical emergency situation with failure of the circulatory system to maintain adequate blood flow to the different organs (shock).
  - swelling, most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body (angioedema).
- 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).

If a side effect occurs, if one of the side effects worsens or if you are suffering from a side effect not mentioned in the leaflet, consult the physician.

<u>Reporting side effects</u>
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (<u>www.health.gov.il</u>) that directs you to the online form for reporting side effects, or by entering the link:
<u>https://sideeffects.health.gov.il</u>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
Store refrigerated (between 2°C to 8°C). Do not freeze.
Store in the original package to protect from light.

6. ADDITIONAL INFORMATION

In addition to the active ingredients, the medicine also contains:
Sodium chloride, disodium phosphate dodecahydrate, polysorbate 80, potassium dihydrogen phosphate, RRR-α-tocopheryl hydrogen succinate, octoxinol 10, potassium chloride, magnesium chloride hexahydrate and water for injections.

What the medicine looks like and the contents of the package:
Fluarix Tetra is a suspension for injection in a pre-filled syringe.

Package sizes: One syringe or ten syringes, with or without needles.
Not all pack sizes may be marketed.

License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.

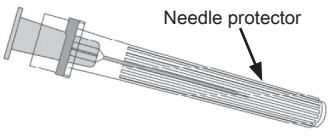
Manufacturer: GlaxoSmithKline Biologicals, Dresden, Germany.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 152-47-34024

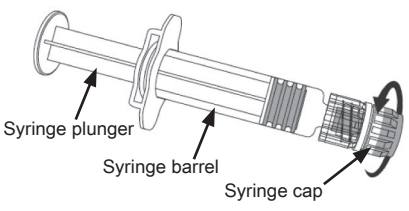
<u>The following information is intended for healthcare professional only</u>:
As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.
Immunisation should be carried 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.

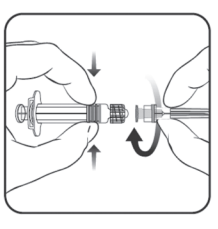
<u>Instructions for administration of the vaccine presented in pre-filled syringe</u>:
To attach the needle to the syringe, refer to the below drawing.

Needle



Syringe





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.

<u>Disposal</u>:
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Revised in September 2024.