

**PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'  
REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a physician's prescription only

## **FLUARIX**

### **Suspension for injection in a pre-filled syringe**

Inactivated influenza vaccine

Each dose (0.5 ml) contains:

Three influenza strains:

**A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238)**

15 micrograms

**A/Croatia/10136RV/2023 (H3N2)-like strain (A/Croatia/10136RV/2023, X-425A)**

15 micrograms

**B/Austria/1359417/2021-like strain (B/Austria/1359417/2021, BVR-26)**

15 micrograms

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

**Read the 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 is indicated for 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 one influenza B virus lineage contained in the vaccine.

The use of Fluarix should be based on official recommendations.

**Therapeutic group:** influenza vaccine.

#### **What is influenza?**

Flu is a disease of the upper airways and lungs caused by infection with a flu virus. The most common symptoms of flu are high temperature, sore throat, coughing, general aches and pains, headache, weakness and tiredness. Complications can occur especially in the very young, the very old, and those with poor immunity to infection.

#### **How the vaccine works?**

The vaccine contains a killed virus that cannot cause flu. Fluarix stimulates the body's immune system to produce antibodies to the specific viruses for which the vaccine was designed. This will help prevent the disease. The vaccine is intended for flu viruses in accordance with official recommendations. As with all vaccines, Fluarix may not fully protect all people who are vaccinated.

## **2. BEFORE USING THE MEDICINE**

### **Do not use the medicine if:**

- you are sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the medicine (see the list in section 6 "Additional information") or to any of the components that may be present in very small amounts, such as ovalbumin (an egg protein), hydrocortisone, gentamicin sulphate, formaldehyde and sodium deoxycholate.

### **Special warnings regarding use of the medicine**

#### **Before treatment with Fluarix, tell the physician if:**

- you have a severe infection with a high temperature. If this happens, the vaccination may need to be delayed until you feel better. A minor infection such as a cold should not be a problem, but talk to the physician or nurse first.
- you have a bleeding problem or a tendency to bruise easily.

Fainting can occur (mostly in adolescents) before or after any needle injection. Therefore, tell the physician or nurse if you fainted after previous injections.

People with a weakened immune system, for example due to HIV (AIDS) infection or due to medicines that suppress the immune system, may not get the full benefit from Fluarix.

If any of the above conditions apply to you (or you are not sure), talk to the physician or nurse before receiving Fluarix.

### **Children and adolescents**

The vaccine is intended for adults and children from 6 months of age. There is no information about the safety and effectiveness of Fluarix in children under 6 months of age. Do not use in children under 6 months of age.

### **Drug interactions**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines, nutritional supplements or other vaccines, tell the physician or pharmacist.**

If Fluarix is given at the same time as other vaccines, a different injection site should be used for each type of vaccine.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are

planning to have a baby, ask the physician or pharmacist for advice before receiving this vaccine.

Inactivated influenza vaccines, such as Fluarix, can be given at any stage of pregnancy. Larger safety datasets are available on vaccine use during the second or third trimesters, compared with the first trimester.

The safety of Fluarix when administered to pregnant women has not been evaluated in clinical trials. Available post-marketing data on Fluarix do not indicate an increased risk of adverse pregnancy outcomes.

It is unknown whether Fluarix is excreted in human milk. No negative effects on breast-fed newborn/infant are anticipated. Fluarix may be given during breast-feeding.

### **Driving and operating machinery**

Some of the side effects mentioned in section 4 “Side effects” below (e.g., fatigue or dizziness) may temporarily have minor influence on the ability to drive and use machines. Do not drive or operate machinery or tools if you do not feel well.

### **Important information about some of the ingredients of the medicine**

#### **Fluarix contains sodium**

The medicine contains less than 1 mmol (23 mg) sodium per dose; namely, it is considered a “sodium-free” medicine.

#### **Fluarix contains potassium**

The medicine contains less than 1 mmol (39 mg) potassium per dose; namely, it is considered a “potassium-free” medicine.

#### **Fluarix contains polysorbate 80**

The medicine contains no more than 0.415 mg polysorbate 80 per dose. Polysorbates may cause allergic reactions. Tell the physician if you have a known allergy to this substance.

## **3. HOW SHOULD THE MEDICINE BE USED?**

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 recommended dosage is generally:  
one injection of 0.5 ml into the muscle.

### **Use in children**

Children less than 9 years of age who have not been vaccinated against flu in the past will receive a second injection at least one month after the first injection. Make sure your child finishes the complete vaccination course. This will maximize the protection offered by Fluarix.

**Do not exceed the recommended dose.**

**Do not take medicines in the dark! Check the label and the dose each time 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 may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. Ask the physician or nurse if you are interested in more information about possible side effects of Fluarix.

**Side effects that have been reported during general use of Fluarix include:**

### **Serious side effects**

Tell the physician straight away if you notice any of the following serious side effects; you may need urgent medical treatment.

**Rare side effects (occur with up to 1 in 1,000 doses of the vaccine):**

- Severe allergic reactions (anaphylactic reactions). These can be recognized by:
  - itchy rash of the hands and feet
  - swelling of the eyes and face
  - difficulty in breathing or swallowing
  - sudden drop in blood pressure and loss of consciousness

These effects usually occur within 15 minutes after vaccination. However, if you get any of these signs, you should contact a physician urgently.

### **Other side effects**

Tell the physician or nurse if you notice any of the following side effects:

**Rare side effects (occur with up to 1 in 1,000 doses of the vaccine):**

- Nerve inflammation (neuritis), inflammation of the brain and spinal cord (encephalomyelitis), temporary inflammation of the nerves, causing pain, weakness and paralysis, called Guillain-Barré syndrome
- Skin reactions that may spread throughout the body, including itchiness (pruritus, urticaria) and redness of the skin (erythema), rash
- Temporary swelling of the glands in the neck, armpit or groin (transient lymphadenopathy)
- Flu-like symptoms, generally feeling unwell

**Side effects that were reported during clinical studies with Fluarix:**

**Side effects that occurred in children 6 months to less than 6 years of age**

**Very common side effects (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
- Swelling at the injection site

**Common side effects (occur with up to 1 in 10 doses of the vaccine):**

- Feeling sick
- Vomiting
- Diarrhoea
- Stomach pain
- Fever

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

**Very common side effects (occur with more than 1 in 10 doses of the vaccine):**

- Headache
- Muscle pain
- Fatigue
- Pain at the injection site
- Redness at the injection site
- Swelling at the injection site

**Common side effects (occur with up to 1 in 10 doses of the vaccine):**

- Feeling sick
- Vomiting
- Diarrhoea
- Stomach pain
- Joint pain
- Shivering
- Fever

**Side effects that occurred in adults 18 years of age and older**

**Very common side effects (occur with more than 1 in 10 doses of the vaccine):**

- Pain at the injection site
- Fatigue
- Headache
- Aching muscles

**Common side effects (occur with up to 1 in 10 doses of the vaccine):**

- Redness, swelling or a hard lump at the injection site
- Shivering
- Sweating
- Joint pain
- Feeling sick
- Vomiting
- Diarrhoea

- Stomach pain

**Uncommon side effects (occur with up to 1 in 100 doses of the vaccine):**

- Fever
- Dizziness

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

**Reporting side effects**

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 ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

## **5. HOW SHOULD THE MEDICINE BE STORED?**

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe 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 in a refrigerator (between 2°C and 8°C). Do not freeze.
- Store in the original package to protect from light.
- Do not discard medicines in the wastewater or household waste. Consult the pharmacist about how to dispose of medicines that are not in use. These measures will help protect the environment.

## **6. ADDITIONAL INFORMATION**

- In addition to the active ingredients, the medicine also contains:  
Sodium chloride, disodium hydrogen phosphate dodecahydrate, polysorbate 80, potassium dihydrogen phosphate, RRR- $\alpha$ -tocopheryl hydrogen succinate, potassium chloride, octoxinol 10, magnesium chloride hexahydrate and water for injections.
- What the medicine looks like and the contents of the package: Fluarix is a suspension for injection in a pre-filled syringe.
  - Fluarix is a colourless and slightly opalescent liquid.
  - Package sizes: one 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 S.A., Rixensart, Belgium.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 179-96-38199-00

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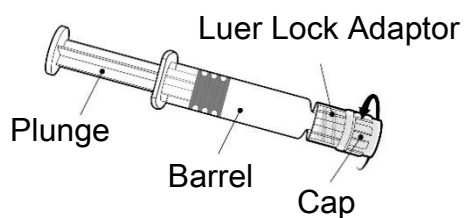
The following information regarding administration of the vaccine is intended for healthcare professionals only:

Vaccines should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to administration.

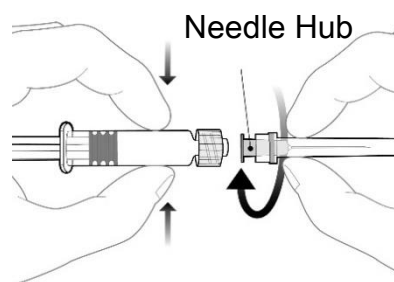
Before use, the vaccine should be well shaken to obtain a colourless and slightly opalescent liquid. Discard if the content appears otherwise.

The entire contents of the syringe should be injected.

#### Instructions for the pre-filled syringe



Hold the syringe by the barrel, not by the plunger.  
Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, connect the hub to the Luer Lock Adaptor and rotate a quarter turn clockwise until you feel it lock.  
Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

#### Disposal

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

Approved in August 2025

*Fluarix PT V1B*