PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

FluMist® Quadrivalent

Intranasal Spray

Composition:

Each 0.2 ml pre-filled nasal sprayer contains:

$10^{7.0\pm0.5}$ FFU (fluorescent focus units) of live attenuated influenza virus reassortants of each of the four strains for the 2022-2023 season:

A/Victoria/2570/2019 (H1N1)pdm09 - like strain (A/Victoria/1/2020)

A/Darwin/9/2021 (H3N2) - like strain (A/Norway/16606/2021)

B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013)

B/Austria/1359417/2021 - like strain (B/Austria/1359417/2021)

For inactive ingredients please refer to section 6 – further information.

Read this leaflet carefully in its entirety before you start taking this medication.

Keep this leaflet. You may need it again.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

FluMist Quadrivalent is a vaccine that is sprayed into the nose to help protect against influenza. This vaccine provides protection against four strains of the influenza virus. The vaccine can be used to vaccinate children, adolescents and adults aged 2 through 49 years.

Therapeutic group

Live influenza vaccine.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are or have ever been hypersensitive to eggs or egg proteins (e.g. ovalbumin), gentamicin, gelatin, arginine, or to any components of the vaccine.
- If you have ever had a life-threatening reaction to previous influenza vaccinations.
- In children and adolescents, 2-17 years of age, who are taking aspirin or medicines that contain aspirin.
- Children or adolescents should not be given aspirin for 4 weeks after getting the FluMist Quadrivalent vaccine unless the attending doctor tells you otherwise.
- Please speak with your doctor if you are uncertain if any of these relate to you.
- Do not administer this vaccine to children younger than 24 months of age. Children under 2 years old have an increased risk of wheezing (difficulty with breathing) after getting FluMist Quadrivalent.

Special warnings regarding use of FluMist Quadrivalent

If you are sensitive to any food or medicine, inform the doctor before taking this medicine.

The vaccine has not been studied in patients with severe asthma and patients with a severely weakened immune system.

Before you are given FluMist Quadrivalent tell your doctor if you or your child:

- are currently wheezing, suffer from asthma.
- have a history of wheezing if under 5 years old.
- have had Guillain-Barré syndrome.
- have a weakened immune system or live with someone who has a severely weakened immune system.
- have problems with your heart, kidneys, lungs.
- have diabetes.
- are pregnant.
- are breastfeeding.
- are taking Tamiflu®, Relenza®, amantadine, or rimantadine.

Drug interactions:

If you are taking or have recently taken any other medicines including non-prescription medicines and food supplements, tell the doctor or pharmacist. Especially, inform your doctor or pharmacist if you are taking aspirin or medicines containing aspirin (if 2 to 17 years old), antiviral agents that are active against influenza A or B viruses, nasal medications or any other vaccines.

Pregnancy, breastfeeding and fertility:

If you are pregnant, think you may be pregnant, plan to become pregnant or are breast-feeding, consult your doctor or pharmacist before receiving this vaccine.

3. HOW SHOULD YOU USE THE MEDICINE?

- FluMist Quadrivalent is a liquid. It should be sprayed only into the nose.
- You can breathe normally while getting FluMist Quadrivalent. There is no need to inhale or "sniff" it.
- People 9 years of age and older need one dose of FluMist Quadrivalent each year.
- Children 2 through 8 years old may need 2 doses of FluMist Quadrivalent, depending on their history of previous influenza vaccination. The attending doctor will decide if your child needs to come back for a second dose.
- The vaccine will be administered by a doctor or nurse. Before administering the vaccine, the doctor or nurse will refer to the detailed instructions in the Physician's Leaflet.
- FluMist Quadrivalent contains a dose of 0.2 ml. 0.1 ml will be administered in each nostril.
- Dose is according to your doctor's instructions only. Do not exceed the recommended dose.
- If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

4. SIDE EFFECTS

As with any medicine, use of FluMist Quadrivalent may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

In addition to the desired effect of the medicine, adverse reactions may occur when using it, such as:

Side effects that require special attention, refer immediately to your doctor or emergency room if you or your child has one of the following symptoms:

- hives or bad rash,
- difficulty breathing,
- swelling of the face, tongue or throat.

The most common side effects of FluMist Quadrivalent are:

- runny or stuffy nose,
- sore throat,
- fever over 37.78°C.

Other possible side effects include:

- decreased appetite,
- irritability,
- tiredness,
- cough,
- headache,
- muscle ache,
- chills.

If any of the side effects worsens, or if you experience side effects not mentioned in the leaflet, consult the doctor.

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) that directs you to the online form for reporting side effects, or by entering the link:

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

5. HOW SHOULD FLUMIST QUADRIVALENT BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor!
- Do not use the medicine after the expiry date (exp. date) that appears on the package.
- Store in a refrigerator between 2°C-8°C (do not freeze).
- Keep the sprayer in carton until used, in order to protect from light.

6. FURTHER INFORMATION

Composition: In addition to the active substances, this medicine also contains:

Sucrose, Arginine Hydrochloride, Dibasic Potassium Phosphate, Gelatin Hydrolysate (Porcine Type A), Monobasic Potassium Phosphate, Monosodium Glutamate, Water for Injection.

Each dose may contain residual amounts of egg protein (ovalbumin), residual amounts of gentamicin sulfate (antibiotics) and also residual amounts of EDTA.

Each dose contains 13.68 mg sucrose.

What the medicine looks like and contents of the pack

The package contains 10 prefilled sprayers for intranasal administration only. Each sprayer contains one dose of 0.2 ml (0.1 ml per nostril).

License Number: 150-69-33985-00

Manufacturer:

MedImmune LLC, Gaithersburg, USA.

License Holder and Importer:

AstraZeneca (Israel) Ltd.,

1 Atirei Yeda St., Kfar Saba, 4464301.

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