

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

This medicine is dispensed with a doctor's prescription only

FluMist®

Nasal Spray, Suspension

Composition:

Each 0.2 ml pre-filled nasal sprayer contains:

107.0±0.5 FFU (fluorescent focus units) of live attenuated influenza virus reassortants of each of the three strains for 2025-2026 season:

A/Victoria/4897/2022 (H1N1) pdm09 - like strain (A/Norway/31694/2022)

A/Croatia/10136RV/2023 (H3N2) - like strain (A/ Perth/722/2024)

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.

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 is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

FluMist is approved for use in persons 2 through 49 years of age.

Therapeutic group

Live influenza vaccine.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You have or have had a hypersensitivity to eggs or egg proteins (e.g. ovalbumin), gentamicin, gelatin, arginine, or to any of the vaccine ingredients.
- You have ever had severe allergic 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 vaccine unless the attending doctor tells you otherwise.

Please speak with your doctor if you are uncertain if any of above 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.

Special warnings regarding use of FluMist

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 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 antiviral drugs for the treatment of influenza.

If you or your child cannot take FluMist, you may still be able to get an influenza vaccine. Talk to your healthcare provider about this.

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.

Pregnancy and breastfeeding:

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.

Driving and using machines

FluMist has no or negligible influence on the ability to drive and use machines.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure regarding the dosage and manner of treatment with this medicine.

- FluMist is a liquid. It should be sprayed only into the nose.
- You can breathe normally while getting FluMist. There is no need to inhale or "sniff" it.
- People 9 years of age and older need one dose of FluMist each year.
- Children 2 through 8 years old may need 2 doses of FluMist, 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 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.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of FluMist 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.

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.

Common side effects (effects occurring in more than 1 of 10 users):

- 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 a side effect occurs, 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 TO STORE THE MEDICINE?

- 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

In addition to the active substances, FluMist 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.

What the medicine looks like and contents of the pack

This vaccine is presented as a nasal spray suspension ready for use, for intranasal administration only, in a pack containing one sprayer or ten sprayers.

Each sprayer contains one dose of 0.2 ml (0.1 ml per nostril).

Not all pack sizes may be marketed.

License Number: 177-71-38099

Manufacturer:

MedImmune LLC, Gaithersburg, USA.

License Holder and Importer:

AstraZeneca (Israel) Ltd.,

1 Atirei Yeda St., Kfar Saba, 4464301.

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