

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

FLUMIST® influenza vaccine (live, attenuated)

This Patient Medication Information is written for the person who will be taking **FLUMIST**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **FLUMIST**, talk to a healthcare professional.

What FLUMIST is used for:

- FLUMIST is a vaccine used to prevent the flu in people between 2 to 59 years of age.

How FLUMIST works:

FLUMIST is a vaccine against the flu. The vaccine is made from strains of the flu that are expected to come within the next year in North America.

The ingredients in FLUMIST are:

Medicinal ingredient: Influenza vaccine (live, attenuated)

Non-medicinal ingredients: Arginine hydrochloride, dibasic potassium phosphate, gelatin hydrolysate (porcine Type A), gentamicin (a trace residual), monobasic potassium phosphate, monosodium glutamate, ovalbumin (a trace residual) and sucrose.

FLUMIST contains no preservatives (e.g. no thimerosal). The intranasal sprayer contains no latex.

FLUMIST comes in the following dosage form:

FLUMIST is a 0.2 mL spray for nasal administration.

Each 0.2 mL dose contains $10^{6.5-7.5}$ FFU (fluorescent focus units) of live attenuated influenza virus reassortants of each of the three virus strains for the specific season. The three strains used for the 2025-2026 season are: A/Norway/31694/2022 (H1N1) (A/Victoria/4897/2022 (H1N1)pdm09-like virus), A/Perth/722/2024 (H3N2) (A/Croatia/10136RV/2023 (H3N2)-like virus) and B/Austria/1359417/2021 (Victoria lineage).

Do not use FLUMIST if you or your child(ren) have:

- Had an allergic reaction to gentamicin (a trace residual), gelatin, arginine or any of the other ingredients contained in FLUMIST.
- Ever had a **severe allergic reaction** to eggs or egg proteins.
- Had an allergic reaction to previous flu vaccination.

To help avoid side effects and ensure proper use, talk to your or your child's healthcare professional before you or your child(ren) take FLUMIST. Talk about any health conditions or problems you may have, including if you or your child(ren):

- Are under 18 years of age receiving aspirin or medicines containing aspirin.

- Have severe asthma or active wheezing.
- Have had Guillain-Barré syndrome with a previous flu shot.
- Are immunosuppressed due to disease or drug treatment, or associate with people who are immunosuppressed.
- Are pregnant or intend to become pregnant or are nursing.

Tell your or your child's healthcare professional about all the medicines you or your child(ren) take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with FLUMIST:

- *if 2 to under 18 years old:* aspirin or medicines containing aspirin.
- prescription medicines used to treat flu.

How to take FLUMIST:

FLUMIST may be taken by you, or given by your caregiver under the supervision of a healthcare professional, or may be given by a healthcare professional.

In children and adolescents 2 to under 18 years of age, FLUMIST should be administered by either their caregiver under the supervision of a healthcare professional or by a healthcare professional.

Before FLUMIST is self-administered or administered by a caregiver under the supervision of a healthcare professional, read the INSTRUCTIONS FOR USE.

FLUMIST is needle-free. FLUMIST must only be used as a nasal spray. FLUMIST must not be injected.

FLUMIST is a gentle mist and will be given as a spray in each nostril. You can breathe normally while FLUMIST is being given. There is no need to actively inhale or sniff.

Administration: FLUMIST is administered by quickly spraying approximately one-half of the contents into each nostril. Please refer to the diagram below for simple step-by-step administration instructions. Once FLUMIST has been administered, the sprayer should be disposed of according to the standard procedures for medical waste (e.g., sharps container or biohazard container).

Figure 1

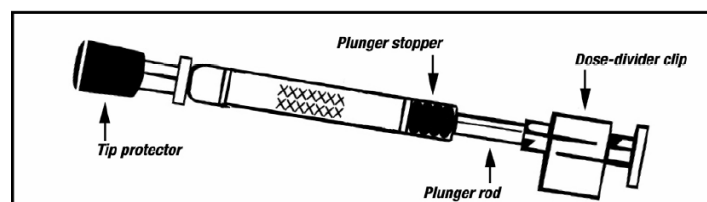
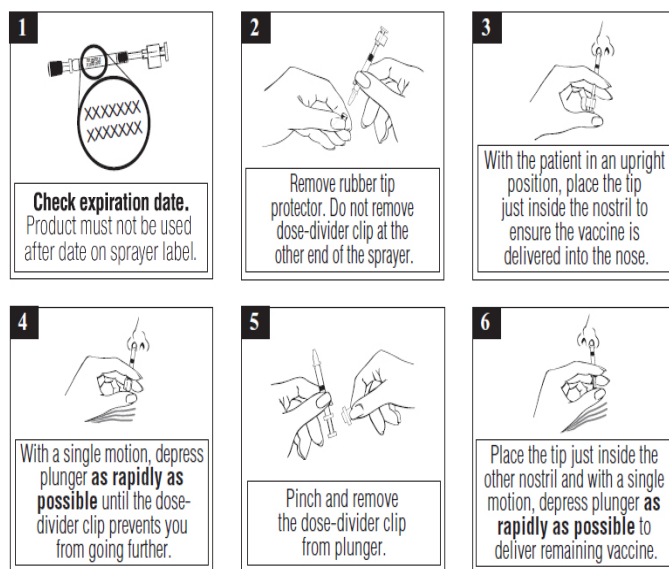


Figure 2



 **DO NOT INJECT. DO NOT USE A NEEDLE.**

Note: Active inhalation (i.e., sniffing) is not required by the patient during vaccine administration.

Usual dose:

One 0.2 mL dose of FLUMIST per year; about one-half of the contents will be sprayed into each nostril.

Children (2-8 years) who have not previously been vaccinated with the flu shot should receive a second dose 4 weeks after the first dose.

Overdose:

There is no relevant information available on overdose with FLUMIST vaccine.

If you think you, or a person you are caring for, have taken too much FLUMIST, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Possible side effects from using FLUMIST:

These are not all the possible side effects you or your child may have when taking FLUMIST. If you or your child(ren) experience any side effects not listed here, tell your or your child's healthcare professional.

Very common (occurs in more than 1 in 10 people)

- **Children:** runny or stuffy nose, reduced appetite, weakness, headache, and fever.
- **Adults:** runny or stuffy nose, headache, sore throat, weakness and cough.

Common (occurs in less than 1 in 10 people)

- **Children:** muscle aches
- **Adults:** chills

Uncommon (occurs in less than 1 in 100 people)

- rash
- nose bleed

Rare (occurs in less than 1 in 1,000 people)

- allergic reactions

Very rare (occurs in less than 1 in 10,000 people)

- Guillain-Barré syndrome

Unknown

- worsening of symptoms of Leigh syndrome

If you or your child(ren) have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your or your child's healthcare professional.

Reporting suspected side effects for vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada (PHAC), Health Canada (HC), and AstraZeneca Canada Inc. cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory ([Reporting Adverse Events Following Immunization \(AEFI\) in Canada](#)) and send it to your local Health Unit.

Storage:

- FLUMIST must be stored in a refrigerator (2°C – 8°C) upon receipt and until use. DO NOT FREEZE.
- FLUMIST may be kept at room temperature between 20°C to 25°C in its carton for a maximum of 12 hours.
- Keep the nasal sprayer in the outer carton in order to protect from light.
- Use FLUMIST before the expiry date on the sprayer label.

Keep out of reach and sight of children.

If you want more information about FLUMIST:

- Talk to your or your child's healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](#)); the manufacturer's website www.astrazeneca.ca; or by calling 1-800-668-6000.

This leaflet was prepared by AstraZeneca Canada Inc., Mississauga, Ontario L4Y 1M4.

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INSTRUCTIONS FOR USE
FLUMIST®
influenza vaccine (live, attenuated)

Nasal spray, suspension

This “Instructions for Use” contains information on how to use the FLUMIST sprayer.

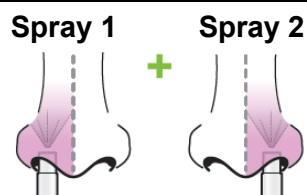
Read this ‘Instructions for Use’ before using FLUMIST. Even if you have previously used FLUMIST, there may be new information. This information does not take the place of talking to your healthcare professional about your medical history and whether or not FLUMIST is right for you or your child.

If you or your caregiver have any questions, talk to your healthcare professional.

Each FLUMIST Nasal Sprayer Contains 1 Dose

1 Dose = 2 Sprays

1 spray for each nostril.



IMPORTANT: DO NOT remove the dose divider clip until **Step 7**.

Important Information You Need to Know Before Using FLUMIST

DO NOT use FLUMIST if:

- It has been frozen.
- It has been dropped and/or damaged.
- The carton has been opened, damaged, or appears tampered with.
- The expiration date (EXP) has passed.

If any of the above happens, follow **Step 11** and contact your healthcare professional.

- **DO NOT** use FLUMIST in the eyes, mouth, or on your skin.
- **DO NOT** share FLUMIST with anyone or reuse the sprayer.
- **DO NOT** inject FLUMIST.

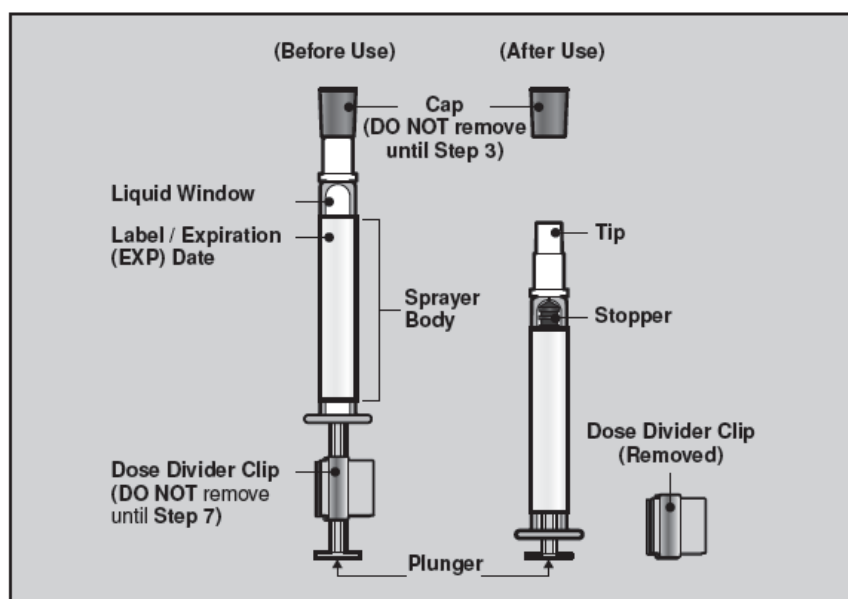
Contact your healthcare professional if you have any questions.

Storing FLUMIST

- Keep FLUMIST and all medicines out of reach of children.
- Store FLUMIST in a refrigerator between 2°C to 8°C in its carton to protect from light until you are ready to use it.

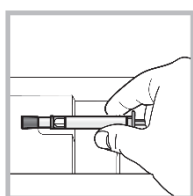
- FLUMIST may be kept at room temperature between 20°C to 25°C in its carton for a maximum of 12 hours.
- **DO NOT** freeze FLUMIST.
- **DO NOT** expose to temperatures greater than 25°C.

FLUMIST Nasal Sprayer



Prepare to Use FLUMIST

Step 1



Remove the FLUMIST carton from the refrigerator and place on a clean flat surface.

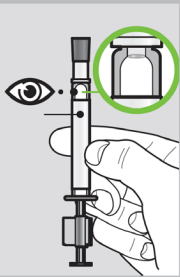
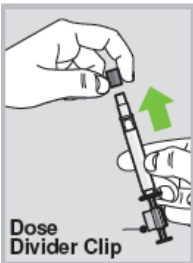
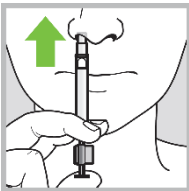
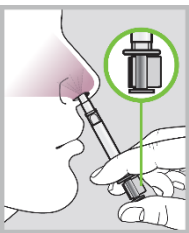
- Use FLUMIST within **12 hours** of removing from the refrigerator. Check the carton.

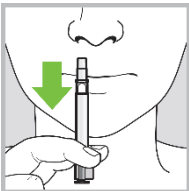
- **DO NOT** use FLUMIST if the expiration (EXP) date has passed.
- **DO NOT** use if the carton has been opened, damaged, or appears tampered with.

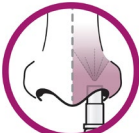
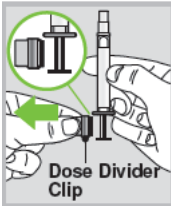
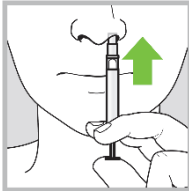
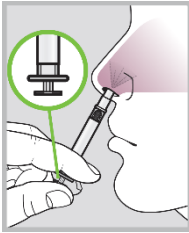
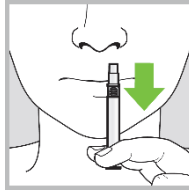
Open the carton and remove the FLUMIST sprayer by holding onto the sprayer body.

- **DO NOT** hold the sprayer by any other component.

Step 2

	Check the FLUMIST sprayer. The liquid should be clear and colourless to slightly yellow. • DO NOT use if the liquid appears discoloured. • DO NOT attempt to remove bubbles from the sprayer. • DO NOT use FLUMIST if the expiration (EXP) date on the label has passed. • DO NOT use if the sprayer appears damaged.
	Spray 1
Step 3	
	Hold on to the sprayer body and pull off the gray cap. • DO NOT remove the dose divider clip until Step 7. • DO NOT push or pull the plunger. • DO NOT prime or remove bubbles from the sprayer. • DO NOT insert the sprayer into nostril before removing the cap.
Step 4	
	Keeping head in upright position, place just the sprayer tip inside one nostril. The sprayer tip does not need to be inserted far into the nose. • DO NOT insert the entire white tip inside the nostril.
Step 5	
	Administer Spray 1 by pushing the plunger as quickly as possible until it stops at the dose divider clip. • DO NOT remove sprayer until the plunger has stopped. • DO NOT remove the dose divider clip until Step 7. • Breathe normally. There is no need to inhale or sniff. • It is normal if you feel a slight tickle or experience some dripping or sneezing.
Step 6	

	Remove the sprayer from the first nostril. Wipe away any liquid that drips from the nose with a tissue. IMPORTANT: Continue to Spray 2 (Step 7).
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	Spray 2	
Step 7		
	Holding onto the sprayer body, pinch and remove the dose divider clip from plunger. DO NOT push or pull the plunger.	
Step 8		
	Keeping head in upright position, place just the sprayer tip inside the other nostril. The sprayer tip does not need to be inserted far into the nose. DO NOT insert the entire white tip inside the nostril.	
Step 9		
	Administer Spray 2 by pushing the plunger as quickly as possible until it stops. DO NOT remove sprayer until the plunger has stopped. - Breathe normally. There is no need to inhale or sniff. - It is normal if you feel a slight tickle or experience some dripping or sneezing.	
Step 10		
	Remove the sprayer from the second nostril. Wipe away any liquid that drips from the nose with a tissue.	

Step 11	
	Dispose of the used sprayer safely as instructed by your healthcare professional.

For more information, go to www.astrazeneca.ca or call 1-800-668-6000. If you still have questions, contact your healthcare professional.

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