

PART III: CONSUMER INFORMATION
FLUMIST®
INFLUENZA VACCINE (LIVE, ATTENUATED)

This leaflet is part III of a three-part "Product Monograph" published when FLUMIST was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about FLUMIST. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

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

What it does:

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.

When it should not be used:

Do not take FLUMIST if you have had an allergic reaction to any of the ingredients contained in FLUMIST, especially to eggs, to egg proteins, gentamicin (a trace residual), gelatin, or arginine. Do not take FLUMIST if you have had an allergic reaction to previous flu vaccination.

What the medicinal ingredient is:

Influenza vaccine (live, attenuated)

What the important nonmedicinal ingredients are:

Gelatin hydrolysate (porcine Type A), sucrose, arginine and gentamicin.

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

For a full listing of non-medicinal ingredients see Part 1 of the Product Monograph.

What dosage forms it comes in:

FLUMIST is a 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 2012-2013 season are: A/California/7/2009 (H1N1)pdm09, A/Victoria/361/2011 (H3N2), and B/Wisconsin/1/2010.

WARNINGS AND PRECAUTIONS

BEFORE you use FLUMIST, talk to your doctor or pharmacist if you or your child (ren):

- are under the age of 18 years 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

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with FLUMIST include:

- *if 2 to 17 years old:* aspirin or medicines containing aspirin
- prescription medicines used to treat flu

PROPER USE OF THIS MEDICATION

FLUMIST is given by health care professionals.

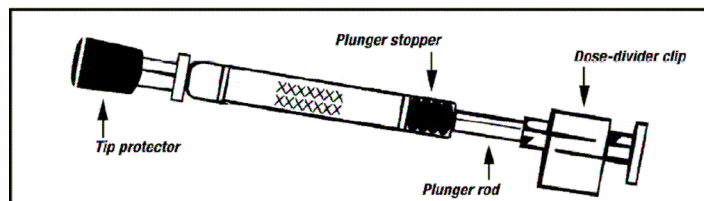
FLUMIST is needle-free. FLUMIST must only be used as a nasal spray. FLUMIST must not be injected.

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:

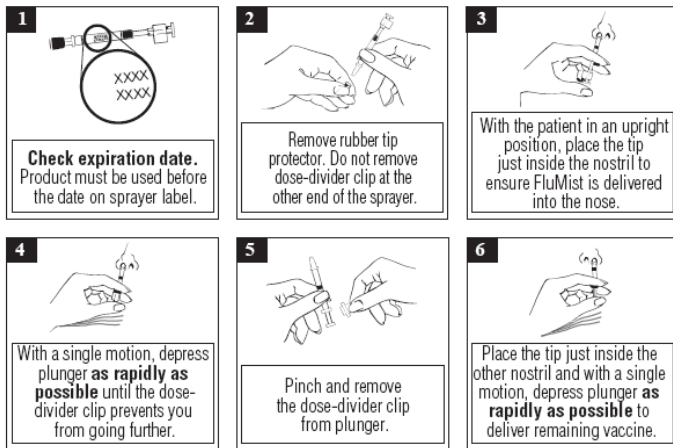
FLUMIST is administered by quickly spraying approximately one-half of the contents into each nostril. Please refer to the diagram below for simple step-by-step administration instructions. Once FLUMIST has been administered, the sprayer should be disposed of according to the standard procedures for medical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

Figure 1



IMPORTANT PLEASE READ

Figure 2



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

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

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, FLUMIST can cause side effects, although not everybody gets them. Ask your doctor, nurse or pharmacist if you want more information about possible side effects from FLUMIST.

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

This is not a complete list of side effects. For any unexpected effects while taking FLUMIST, contact your doctor or pharmacist.

HOW TO STORE IT

FLUMIST must be stored in a refrigerator (2°C – 8°C) upon receipt and until use. **DO NOT FREEZE.**

Use FLUMIST as indicated by the expiry date on the sprayer label.

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REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

For health care professionals:

If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in your province/territory.

For the General Public:

Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada

By toll-free telephone: 866-844-0018

By toll-free fax: 866-844-5931

Email: caefi@phac-aspc.gc.ca

Web: <http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php>

Mail:

The Public Health Agency of Canada

Vaccine Safety Section

130 Colonnade Road

A/L 6502A

Ottawa, ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

MORE INFORMATION

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing. For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at:

www.astrazeneca.ca,

or by contacting the sponsor, AstraZeneca Canada Inc. at:

Customer Inquiries – 1 (800) 668-6000

Renseignements – 1 (800) 461-3787

This leaflet was prepared by:

AstraZeneca Canada Inc. Mississauga, Ontario L4Y 1M4

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