

PART III: CONSUMER INFORMATION
FLUMIST® QUADRIVALENT
influenza vaccine (live, attenuated)

This leaflet is part III of a three-part "Product Monograph" published when FLUMIST QUADRIVALENT 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 QUADRIVALENT. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
 FLUMIST QUADRIVALENT is a vaccine used to prevent the flu in people between 2 to 59 years of age.

What it does:
 FLUMIST QUADRIVALENT 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 QUADRIVALENT if you:

- have had an allergic reaction to gentamicin (a trace residual), gelatin, arginine or any of the other ingredients contained in FLUMIST QUADRIVALENT.
- have ever had a **severe allergic reaction** to eggs or egg proteins.
- 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 QUADRIVALENT 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 QUADRIVALENT 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 four virus strains for the specific season. The four strains used for the 2018-2019 season are: A/Michigan/45/2015 (H1N1)pdm09-like strain (A/Slovenia/2903/2015), A/Singapore/INFIMH-16-0019/2016 (H3N2), B/Phuket/3073/2013 (Yamagata lineage), and B/Colorado/06/2017 (Victoria lineage).

WARNINGS AND PRECAUTIONS

BEFORE you use FLUMIST QUADRIVALENT, 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 QUADRIVALENT include:

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

PROPER USE OF THIS MEDICATION

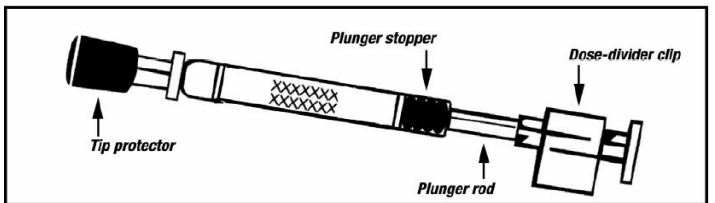
FLUMIST QUADRIVALENT is given by health care professionals.

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

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

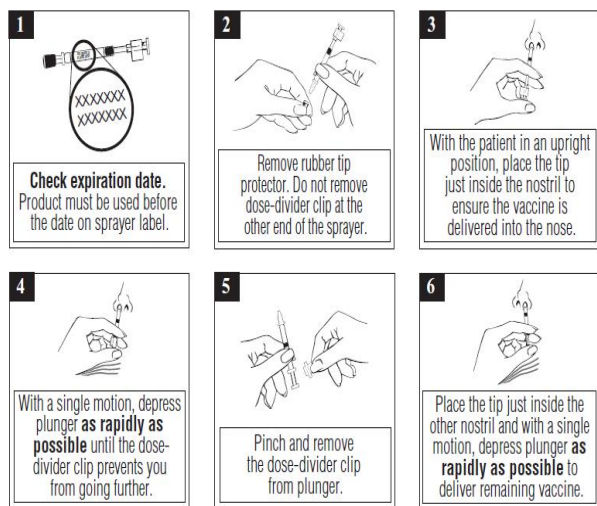
Administration:
 FLUMIST QUADRIVALENT is administered by quickly spraying approximately one-half of the contents into each nostril. Please refer to the diagram below for simple step-by-step administration instructions. Once FLUMIST QUADRIVALENT has been administered, the sprayer should be disposed of 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 vaccine administration.

Usual dose:

One 0.2 mL dose of FLUMIST QUADRIVALENT 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 QUADRIVALENT 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 QUADRIVALENT 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 QUADRIVALENT.

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 QUADRIVALENT, contact your doctor or pharmacist.

HOW TO STORE IT

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

Keep the nasal sprayer in the outer carton in order to protect from light.

Use FLUMIST QUADRIVALENT before the expiry date on the sprayer label.

REPORTING SUSPECTED SIDE EFFECTS

For the general public: Should you experience a side effect following immunization, please report it to your doctor, nurse, or pharmacist.

Should you require information related to the management of the side effect, please contact your healthcare provider. The Public Health Agency of Canada, Health Canada 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 (<http://www.phac-aspc.gc.ca/im/aeffi-form-eng.php>) and send it to your local Health Unit.

MORE INFORMATION

This Consumer Information leaflet is current at the time of printing. The most current Consumer Information leaflet and Product Monograph are available at:

www.astrazeneca.ca, or by calling the sponsor, AstraZeneca Canada Inc. at: 1-800-668-6000.

This leaflet was prepared by:

AstraZeneca Canada Inc. Mississauga, Ontario L4Y 1M4
FLUMIST QUADRIVALENT is manufactured by MedImmune, LLC

FLUMIST® is a registered trademark of MedImmune, LLC, used under license by AstraZeneca Canada Inc.
The AstraZeneca logo is a registered trademark of AstraZeneca AB, used under license by AstraZeneca Canada Inc.

©AstraZeneca 2014-2018

Last revised: April 19, 2018