FluMist® Quadrivalent Influenza Vaccine Live, Intranasal

Health Care Provider Resource Frequently Asked Questions

FLUMIST® QUADRIVALENT (Influenza Vaccine Live, Intranasal)

INDICATION

FLUMIST QUADRIVALENT is a vaccine indicated for active immunization of persons 2-49 years of age for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. FLUMIST QUADRIVALENT is for intranasal administration only.

IMPORTANT SAFETY INFORMATION

- FLUMIST QUADRIVALENT is contraindicated in persons who have had a severe allergic reaction (eg, anaphylaxis) to any vaccine component, including egg protein, or after a previous dose of any influenza vaccine, and in children and adolescents receiving concomitant aspirin or aspirin-containing therapy
- In clinical trials, the risks of hospitalization and wheezing were increased in children <24 months of age who received trivalent FluMist
- Children <5 years of age with recurrent wheezing and persons of any age with asthma may be at increased risk of wheezing following FLUMIST QUADRIVALENT administration. FLUMIST QUADRIVALENT has not been studied in persons with severe asthma or active wheezing
- If Guillain-Barré syndrome has occurred within 6 weeks of any prior influenza vaccination, the decision to give FLUMIST QUADRIVALENT should be based on careful consideration of the potential benefits and risks
- FLUMIST QUADRIVALENT has not been studied in immunocompromised persons
- The safety of FLUMIST QUADRIVALENT in individuals with underlying medical conditions predisposing them to wild-type influenza infection complications has not been established
- Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine
- FLUMIST QUADRIVALENT may not protect all individuals receiving the vaccine
- The most common solicited adverse reactions (occurring ≥10% in vaccine recipients and at least 5% greater than in placebo) reported were runny nose or nasal congestion in persons 2-49 years, fever >100°F in children 2-6 years, and sore throat in adults 18-49 years. Among children 2-17 years who received FLUMIST QUADRIVALENT, 32% reported runny nose or nasal congestion and 7% reported fever >100°F. Among adults 18-49 years who received FLUMIST QUADRIVALENT, 44% reported runny nose or nasal congestion and 19% reported sore throat

Please see accompanying full Prescribing Information for FLUMIST QUADRIVALENT, including Patient Information.

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SECTION A: PRODUCT PROFILE

1. What is FLUMIST® QUADRIVALENT?

- FLUMIST® QUADRIVALENT (Influenza Vaccine Live, Intranasal) is a vaccine that is sprayed into the nose to help protect against influenza.[1]
- It can be used in appropriate patients including children, adolescents, and adults aged 2 through 49 years.[1]
- FLUMIST® QUADRIVALENT may not prevent influenza in everyone who gets vaccinated.[1]

2. What is the mechanism of action of FLUMIST® QUADRIVALENT?

- FLUMIST® QUADRIVALENT (Influenza Vaccine Live, Intranasal) starts working where influenza typically enters the body – in the nose.[1,2]
- Immune mechanisms conferring protection against influenza following receipt of FLUMIST® QUADRIVALENT vaccine are not fully understood; serum antibodies, mucosal antibodies, and influenza-specific T-cells may play a role.[1]
- Similar to other live vaccines, like the chicken pox vaccine,[15] FLUMIST® QUADRIVALENT contains a weakened live virus.[1] The weakened live virus is designed not to cause influenza, but to help protect you from influenza. It triggers your immune system to build defenses (called antibodies) throughout the body to help fight against the influenza virus.[1]

3. Who may be a candidate for FLUMIST® QUADRIVALENT?

- FLUMIST® QUADRIVALENT (Influenza Vaccine Live, Intranasal) is approved for persons aged 2 through 49 years. FLUMIST® QUADRIVALENT (Influenza Vaccine Live, Intranasal) **should not be used by**:[1]
    - Persons who have had a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine including egg protein, or after a previous dose of any influenza vaccine.[1]
    - Children and adolescents through 17 years of age who are receiving aspirin therapy or aspirin-containing therapy because of the association of Reye's syndrome with aspirin and wild-type influenza infection.[1]
        - Children or adolescents should not be given aspirin for 4 weeks after getting FLUMIST® QUADRIVALENT unless otherwise directed by a healthcare provider.[1]

4. Contraindications, Warnings, Precautions

a. Who may not be able to get FLUMIST® QUADRIVALENT?

- The following persons should consult their provider before receiving FLUMIST® QUADRIVALENT: those aged 2 through 49 years who are currently wheezing (difficulty with breathing); 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 the heart, kidneys, or lungs; have diabetes; are pregnant or nursing; or are taking a medication used to treat influenza like Tamiflu®*, Relenza®*, amantadine, or rimantadine.[1]
- FLUMIST QUADRIVALENT has not been studied in immunocompromised persons

*Tamiflu and Relenza are registered trademarks of their respective owners.

b. Why is FLUMIST® QUADRIVALENT not recommended for those aged 50 years and over?

- Based on the clinical studies conducted the effectiveness of FLUMIST® QUADRIVALENT (Influenza Vaccine Live, Intranasal) has not been established in people aged 50 years and over.[1] You can find more information about who may and may not be eligible for FLUMIST® QUADRIVALENT in the Prescribing Information: https://www.azpicentral.com/flumistquadrivalent/flumistquadrivalent.pdf, or by calling the AstraZeneca Information Center at 1-800-236-9933.

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5. **Can vaccinating with a live virus cause influenza?**
   - FLUMIST® QUADRIVALENT (Influenza Vaccine Live, Intranasal) is designed not to cause influenza.[1]
   - Like the vaccines for chicken pox and measles,[3] FLUMIST® QUADRIVALENT is a live attenuated vaccine. That means it contains weakened live viruses.[1] A live attenuated vaccine is designed to help stimulate a natural immune response.[4-6]
   - While the mechanism of action is not fully understood, FLUMIST® QUADRIVALENT is thought to provide protection against influenza by driving three different types of immune response: in your nose, your cells, and your bloodstream.[1]

6. **How do I administer FLUMIST® QUADRIVALENT?**
   1. Check expiration date. Product must be used before the date on sprayer label.
   2. Remove rubber tip protector. Do not remove dose-divider clip at the other end of the sprayer.
   3. Place the tip just inside the nostril to ensure FLUMIST QUADRIVALENT is delivered into the nose.
   4. With a single motion, depress plunger as rapidly as possible until the dose-divider clip prevents you from going further.
   5. Pinch and remove the dose-divider clip from the plunger.
   6. Place the tip just inside the other nostril and with a single motion, depress plunger as rapidly as possible to deliver remaining vaccine.
   7. Dispose of sprayer per standard procedures for medical waste (e.g., sharps container).

Please see full Prescribing Information for complete instructions.

7. **Do people have to inhale or actively "sniff" FLUMIST® QUADRIVALENT for it to work?**
   - People who get FLUMIST® QUADRIVALENT (Influenza Vaccine Live, Intranasal) can breathe normally during administration. Sniffing is NOT necessary.[1]

8. **Are there special recommendations for administering FLUMIST® QUADRIVALENT during the COVID-19 pandemic? In addition, is additional personal protective equipment needed when administering FLUMIST® QUADRIVALENT compared with Inactivated Influenza Vaccine (IIV)?**
   - The Centers for Disease Control and Prevention (CDC) has released the Interim Guidance for Routine and Influenza Immunization Services During the COVID-19 Pandemic.[7]
   - The CDC states that immunization providers should refer to the guidance developed to prevent the spread of COVID-19 in healthcare settings, including outpatient and ambulatory care settings.[7]
   - To help ensure the safe delivery of care during vaccination visits, the CDC further states that providers should ensure that all staff adhere to the following infection prevention and control procedures: [7]
     - Follow Standard Precautions, which include guidance for hand hygiene and cleaning the environment between patients.
     - Wear a medical face mask at all times.
     - Use eye protection based on the level of community transmission of the virus that causes COVID-19:
       - Moderate to substantial: Healthcare providers should wear eye protection given the increased likelihood of encountering asymptomatic COVID-19 patients.
       - Minimal to none: Universal eye protection is considered optional, unless otherwise indicated as a part of the standard precautions.
   - The CDC provides additional considerations for the administration of intranasal or oral vaccines: [7]
     - Healthcare providers should wear gloves when administering intranasal or oral vaccines because of the increased likelihood of coming in contact with a patient's mucous membranes and body fluids.
     - Healthcare providers should also change their gloves and wash their hands between patients.
     - As giving these vaccines is not considered an aerosol-generating procedure, the use of an N95 or higher level respirator is not recommended.

9. Are there special precautions that need to be considered when administering FLUMIST® QUADRIVALENT during the COVID-19 pandemic, due to the need to remove/lower the patient's mask during administration?

- Administration of intranasal vaccines is not considered an aerosol-generating procedure. The CDC does not recommend the use of an N95 or higher level respirator.[7] Follow this link for more information.
- As for other vaccination visits, the CDC recommends that providers ensure that all staff adhere to the following infection prevention and control procedures:
  - Follow Standard Precautions, which include guidance for hand hygiene and cleaning the environment between patients.
  - Wear a medical face mask at all times.
  - Use eye protection based on the level of community transmission of the virus that causes COVID-19:
    - Moderate to substantial: Healthcare providers should wear eye protection given the increased likelihood of encountering asymptomatic COVID-19 patients.
    - Minimal to none: Universal eye protection is considered optional, unless otherwise indicated as a part of the standard precautions.

10. Are there any restrictions on use of FLUMIST® QUADRIVALENT in the hospital setting?

- There are no specific recommendations regarding use or restriction of Live Attenuated Influenza Vaccine (LAIV) in the hospital setting.[1]

11. Are there guidelines that inform on which severely immunocompromised individuals should FLUMIST® QUADRIVALENT recipients avoid contact with?

- The FLUMIST Prescribing Information does not contain this information.
- The Advisory Committee on Immunization Practices/CDC has recommendations and you can access that information by referring to this CDC link.
- Those who have a weakened immune system or live with someone who has a severely weakened immune system should consult their healthcare provider before receiving FLUMIST® QUADRIVALENT.[1]

12. What are the most common side effects of FLUMIST® QUADRIVALENT?

- For children aged 2 through 17 years of age, the most common side effects are runny or stuffy nose, sore throat, and fever over 100°F. The most common solicited adverse reactions for adults differ slightly with runny nose or nasal congestion, headache and sore throat being the most common.[1]

SECTION B: STORAGE

13. How is FLUMIST® QUADRIVALENT stored and what is its shelf-life?

- FLUMIST® QUADRIVALENT (Influenza Vaccine Live, Intranasal) should be stored in a refrigerator between 2°C and 8°C and should not be frozen.[1]
- The product must be used before the expiration date on the sprayer label.[1]
- Keep the sprayer in the outer carton to protect from light.[1]
- A single temperature excursion up to 25°C/77°F for 12 hours has been shown to have no adverse impact on the vaccine. After a temperature excursion, the vaccine should be returned immediately to the recommended storage condition (2–8°C/35–46°F) and used as soon as feasible. Subsequent excursions are not permitted.[1]
- FLUMIST® QUADRIVALENT has a shelf-life of 18 weeks once defrosted in the controlled environment by the vaccine supplier.[15] Once FLUMIST® QUADRIVALENT has been administered or has expired, the

sprayer should be disposed of according to the standard procedures for medical waste (e.g., sharps container or biohazard container).[1]

14. Once FLUMIST® QUADRIVALENT has been removed from the fridge, can it be returned to the fridge for later use?

- FLUMIST® QUADRIVALENT should be stored in a refrigerator between 2–8°C/35–46°F upon receipt and until use. The cold chain (2–8°C) must be maintained when transporting FLUMIST® QUADRIVALENT. Do not freeze the product.[1]
- AstraZeneca does not recommend the storage of FLUMIST® QUADRIVALENT in any other manner than as described in the Prescribing Information. The safety and efficacy of FLUMIST® QUADRIVALENT cannot be assured if stored outside the recommended conditions.
- FLUMIST® QUADRIVALENT is designed to be stable at refrigerated temperatures, and it is recommended that FLUMIST® QUADRIVALENT always be stored at refrigerated temperatures (2–8°C/35–46°F) prior to administration.[1]

SECTION C: PUBLIC HEALTH ORGANIZATION, POLICY, AND VACCINE EFFECTIVENESS INFORMATION

15. Does the Advisory Committee on Immunization Practices (ACIP) recommend a specific flu vaccine option more than others?

- The ACIP recommendations state that immunization providers may choose to administer any licensed, age appropriate influenza vaccine including FLUMIST® QUADRIVALENT, Injectable Influenza Vaccine (IIV), and Recombinant Injectable Vaccine (RIV).[9]
- The ACIP specifically voted against a preference for any influenza vaccine during the February 2018 meeting.[13]
- For more information, please visit the official Centers for Disease Control and Prevention (CDC) recommendation on influenza vaccination: https://www.cdc.gov/mmwr/volumes/69/rr/rr6908a1.htm?s_cid=rr6908a1_w

16. Vaccine Effectiveness (VE) Data are something I consider. Can you tell me about VE data that are available for FLUMIST® QUADRIVALENT?

- Countries where live attenuated influenza vaccine (LAIV) was widely used during the 2018–19 season, such as the UK and Finland, have data on VE for LAIV for the 2018–19 influenza season.[14,15]
- An LAIV formulation including the A/Slovenia H1N1 strain was used in the UK during the 2018–19 influenza season.[12] End of season vaccine effectiveness data have been published for the 2018–19 influenza season in the UK.
    - In children aged 2–17 years, adjusted VE with LAIV was 48.6% (95% CI: −4.4 to 74.7) against all circulating strains and 49.9% (95% CI: −14.3 to 78) against circulating A/H1N1pdm09. The study used a test-negative case–control design across primary care influenza sentinel swabbing surveillance schemes in England, Scotland, Wales, and Northern Ireland.[14]

You are encouraged to report negative side effects of AstraZeneca prescription drugs by calling 1-800-236-9933. If you prefer to report these to the FDA, either visit http://www.FDA.gov/medwatch or call 1-800-FDA-1088.

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Please see Important Safety Information on front page and accompanying full Prescribing Information.

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