



FluMist[®] Quadrivalent *Media Backgrounder: FluMist[®] Quadrivalent*

Influenza Vaccine Live, Intranasal

KEY FACTS ABOUT FLUMIST QUADRIVALENT

- FluMist Quadrivalent is approved by the U.S. Food and Drug Administration (FDA) for eligible individuals 2 to 49 years of age.¹
- FluMist Quadrivalent is the **first** and **only** nasal-spray flu vaccine that is FDA-approved to help protect against **four strains of influenza contained in the vaccine** – two strains of influenza A and two strains of influenza B.² It will be available to consumers through their healthcare providers in July 2013 in time for the 2013-2014 flu season. The vaccine's most common side effects are runny or stuffy nose, sore throat, and fever over 100°F.¹
- FluMist Quadrivalent received FDA approval in February 2012 and is manufactured by MedImmune, the global biologics business for AstraZeneca PLC, headquartered in Gaithersburg, Maryland.²
- FluMist Quadrivalent is similar to MedImmune's trivalent influenza vaccine, FluMist[®] (Influenza Vaccine Live, Intranasal), except FluMist Quadrivalent helps provide protection against an additional flu strain contained in the vaccine.¹ FluMist was approved by the FDA in 2003 and more than 63 million doses have been distributed since 2003.³ The same people who are right for FluMist are eligible for FluMist Quadrivalent.¹ When FluMist Quadrivalent ships for the 2013-2014 flu season, it will replace FluMist in the U.S.

Note to Editors/Producers: In your coverage of influenza prevention, please note the terminology “flu shot” is not an accurate way to describe influenza vaccination in general. Please consider the more general term “flu vaccine”

HOW FLUMIST QUADRIVALENT WORKS

- FluMist Quadrivalent is a gentle mist sprayed into the nose, where the influenza virus usually enters the body. It is administered while breathing normally and does not need to be actively “inhaled.”
- FluMist Quadrivalent uses live vaccine virus strains that are weakened so as not to cause the flu. One does not get a case of “the flu” when vaccinated with either the nasal-spray or the injectable influenza vaccine.⁴
- The influenza virus strains in FluMist Quadrivalent, as well as other influenza vaccines in the U.S., are determined each season by the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) and typically follow the recommendations made by the World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC).⁵



WHY FOUR STRAINS?

- There are two lineages of influenza B – B/Victoria and B/Yamagata. Since 2001, these two B lineages have co-circulated each flu season in the U.S.⁶
- Trivalent flu vaccines were designed to protect against three subtypes of influenza viruses that commonly circulate among people today: one influenza B lineage, as well as two strains of influenza A (H1N1 and H3N2).⁷
- Historically, trivalent vaccine formulations have relied on an accurate prediction of which influenza B lineage would be dominant in the season in order to be likely to protect against the predominant circulating B lineage.⁸

- In previous seasons, B-strain prevalence has been difficult to predict correctly. In the U.S., in 6 of the past 12 influenza seasons between 2001-2002 and 2012-2013, the predominant circulating influenza B lineage was different from the one selected for inclusion in the trivalent vaccines.⁹
- Quadrivalent vaccines – like FluMist Quadrivalent – help protect against strains from both the B/Victoria and B/Yamagata lineages, as well as an A (H1N1) strain and an A (H3N2) strain.

PATIENT UPTAKE

- FluMist[®] (Influenza Vaccine Live, Intranasal) is widely used by the U.S. military and in school-located influenza vaccination clinics, as well as by private practice physicians, group healthcare providers, and the federal Vaccines for Children (VFC) program.³
- FluMist Quadrivalent is covered by over 99 percent of health insurance plans with immunization benefits; therefore, most patients who have insurance coverage for immunizations have coverage for FluMist Quadrivalent.³

CLINICAL TRIALS IN CHILDREN AND ADULTS

- In pivotal clinical studies conducted in adults (1,800) and children (2,312), FluMist Quadrivalent was found to have a generally comparable safety profile to two trivalent formulations of MedImmune's licensed seasonal influenza vaccine, FluMist[®].^{10,11}
 - Immunogenicity to individual vaccine strains was comparable in trivalent and quadrivalent formulations. The addition of the second B strain did not result in immune interference with other strains included in the vaccine.^{10,11}
 - In clinical studies comparing FluMist Quadrivalent and FluMist, the most common adverse reactions (≥5 percent in FluMist Quadrivalent and at least 2 percent greater than in FluMist) were runny nose or nasal congestion (adults ages 18 through 49 years), and fever >100°F (children and adolescents ages 2 through 17 years).^{10,11}
- Over 150,000 subjects have received FluMist in pre-approval and post-marketing clinical studies.³
 - In a pivotal study that included more than 4,000 children 2 to 5 years of age during the 2004-2005 influenza season, children who received FluMist were about two times less likely to get the flu compared to those who received the traditional flu shot (4.5 percent vs. 9.8 percent, respectively).^{12,13,14*}
 - In a placebo-controlled clinical trial conducted from 1997-1998 that included 3,600 adults 18 to 49 years of age without high-risk medical conditions, those who received FluMist experienced 20 percent fewer cases of severe febrile illness and 24 percent fewer cases of febrile upper respiratory illness.¹⁵

**Since influenza strains change each year, past clinical trial results do not guarantee future flu season results. Data is representative of the indicated population; full study population is represented in the Prescribing Information.*

IMPORTANT SAFETY AND ELIGIBILITY INFORMATION

What is FluMist[®] Quadrivalent (Influenza Vaccine Live, Intranasal)?

FluMist Quadrivalent is a vaccine that is sprayed into the nose to help protect against influenza. It can be used in children, adolescents, and adults ages 2 through 49. FluMist Quadrivalent is similar to MedImmune's trivalent influenza vaccine, except FluMist Quadrivalent provides protection against an additional influenza strain. FluMist Quadrivalent may not prevent influenza in everyone who gets vaccinated.

Who should not get FluMist Quadrivalent?

You should not get FluMist Quadrivalent if you have a severe allergy to eggs, gentamicin, gelatin, or arginine; have ever had a life-threatening reaction to influenza vaccinations; or are 2 through 17 years old and take aspirin or

medicines containing aspirin – children or adolescents should not be given aspirin for 4 weeks after getting FluMist or FluMist Quadrivalent unless your healthcare provider tells you otherwise.

Children under 2 years old have an increased risk of wheezing (difficulty with breathing) after getting FluMist Quadrivalent.

Who may not be able to get FluMist Quadrivalent?

Tell your healthcare provider if you or your child are currently wheezing; 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, or lungs; have diabetes; are pregnant or nursing; or are taking Tamiflu[®], Relenza[®], amantadine, or rimantadine.

Your healthcare provider will decide if FluMist Quadrivalent is right for you or your child.

What are the most common side effects of FluMist Quadrivalent?

The most common side effects are runny or stuffy nose, sore throat, and fever over 100°F.

Please see the accompanying complete [Product Information, including Patient Information](#) [ PDF] for more information.

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References

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