START HERE

MYTHS vs. FACTS

Start with the facts before you start vaccinating with FluMist® Quadrivalent

M

MYTH:

The live virus strains in FluMist Quadrivalent cause the flu.

F

FACT:

FluMist Quadrivalent contains attenuated viral strains in which the disease-causing properties were modified so as not to cause influenza-like illness (ILI).The virus strains are temperature sensitive, so they have restricted replication at temperatures at which many wild-type influenza viruses grow efficiently. The odds of reversion to wild-type influenza are 1 in 100 quintillion replication cycles (1 x 10^{20} replication cycles). There have been no reported cases involving reversion of a FluMist Quadrivalent vaccine particle to wild-type influenza. Children and young adults 2-17 years of age have reported experiencing adverse reactions after receiving FluMist Quadrivalent, including runny nose, nasal congestion or cough, chills, tiredness/weakness, sore throat, and headache. Adults 18 to 49 years of age have reported runny nose or nasal congestion, cough, chills, tiredness/weakness, sore throat, and headache.

SELECT SAFETY INFORMATION

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.

FluMist Quadrivalent is contraindicated in persons who have had a severe allergic reaction to any vaccine component including egg protein, gentamicin, gelatin and arginine or after a previous dose of any influenza vaccine, and in children and adolescents receiving concomitant aspirin or aspirin-containing therapy.

Please see complete Prescribing Information, including Patient Information.

FluMist® Quadrivalent
Influenza Vaccine Live, Intranasal

MYTHS vs. FACTS

Debunking common myths about FluMist® Quadrivalent

MYTH:
Viral shedding from a person recently vaccinated with FluMist Quadrivalent will transmit the flu virus.

FACT:
In clinical studies with FluMist® (Influenza Vaccine Live, Intranasal), transmission of vaccine viruses to close contacts has occurred only rarely. The current estimated risk of getting infected with vaccine virus after close contact with a person vaccinated with FluMist Quadrivalent is low (0.6%-2.4%). Because the viruses are weakened, infection is unlikely to result in influenza illness symptoms since the vaccine viruses have not been shown to mutate into typical or naturally occurring influenza viruses.

MYTH:
All patients in close contact with immunocompromised persons should not receive FluMist Quadrivalent.

FACT:
Vaccine recipients or their parents/guardians should be informed by the healthcare provider that FluMist Quadrivalent is an attenuated live virus vaccine and has the potential for transmission to immunocompromised household contacts.

According to the CDC/ACIP (Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices), transmission from a recently vaccinated person causing illness in an immunocompromised contact has not, to date, been reported.

The CDC states that people, including healthcare professionals, who are in contact with individuals with weakened immune systems (e.g., people with diabetes, people with asthma taking corticosteroids, or people infected with HIV) can still get FluMist Quadrivalent.

All eligible persons can receive FluMist Quadrivalent, except those who are in close contact with severely immunocompromised persons (e.g., hematopoietic stem cell transplants) during those periods when the immunocompromised persons are in a protective environment.

MYTH:
Healthcare professionals (HCPs) who are pregnant or immunocompromised cannot administer FluMist Quadrivalent.

FACT:
No instances have been reported of illness or attenuated vaccine virus infections among inadvertently exposed HCPs. Although the risk for acquiring vaccine viruses from the environment is unknown, the vaccine viruses are temperature-sensitive, cold-adapted, and attenuated and, therefore, unlikely to cause symptomatic influenza.

Severely immunocompromised individuals should not administer FluMist Quadrivalent. However, other persons at higher risk for influenza complications—including pregnant women, persons with asthma, and persons aged 50 years or older—can administer FluMist Quadrivalent.

MYTH:
FluMist Quadrivalent requires active inhalation (i.e., sniffing) by the patient for proper administration.

FACT:
FluMist Quadrivalent recipients can breathe normally during administration. Sniffing is NOT necessary.

MYTH:
All patients with asthma are not eligible to receive FluMist Quadrivalent.

FACT:
Children younger than 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.

MYTH:
FluMist Quadrivalent is just for children.

FACT:
FluMist Quadrivalent is indicated for eligible individuals ages 2 through 49. FluMist Quadrivalent is similar to FluMist except that FluMist Quadrivalent helps to provide protection against an additional flu strain. The same people who were eligible for FluMist are eligible for FluMist Quadrivalent. In a multicenter, randomized, double-blind, placebo-controlled trial with FluMist in 3,637 adults 18-49 years of age (FluMist, n=2,411; placebo, n=1,226) during the 1997-1998 influenza season, FluMist was effective in reducing cases of influenza-like illness (ILI) vs. placebo. With FluMist Quadrivalent, the most common adverse reactions were runny nose or nasal congestion in recipients of all ages, fever >100°F in children 2 through 6 years of age, and sore throat in adults.

SELECT SAFETY INFORMATION

In clinical trials, the risks of hospitalization and wheezing were increased in children <24 months of age who received 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.

Please see Important Safety Information on back cover.

Please see accompanying complete Prescribing Information, including Patient Information.

FluMist® Quadrivalent
Influenza Vaccine Live, Intranasal

M

MYTH:

If a patient sneezes or blows their nose after receiving FluMist® Quadrivalent, they need to be re-vaccinated.

F

FACT:

Dripping down the throat, sneezing, or swallowing may occur after vaccination. Re-vaccination is not necessary.

M

MYTH:

FluMist Quadrivalent cannot be given to any patient if he or she is ill.

F

FACT:

FluMist Quadrivalent can be given to people with minor illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever). However, if severe nasal congestion is present that might limit delivery of the vaccine to the nasal lining, then delaying of vaccination until the nasal congestion is reduced should be considered. Antiviral drugs that are active against influenza A and/or B viruses may reduce the effectiveness of FluMist Quadrivalent if administered within 48 hours before, or within 2 weeks after vaccination. There is no data regarding co-administration of FluMist Quadrivalent with other intranasal preparations.

SELECT SAFETY INFORMATION

In clinical trials, the risks of hospitalization and wheezing were increased in children <24 months of age who received FluMist® (Influenza Vaccine Live, Intranasal). 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. 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 after FluMist were runny nose or nasal congestion in all 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 complete Prescribing Information, including Patient Information.

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