IMPORTANT UPDATE REGARDING PRODUCT EXPIRY

FLUMIST® QUADRIVALENT (Influenza Vaccine Live, Intranasal)
NDC: 66019-310-10
Lot: TH2989 and TH2989B

Dear Healthcare Provider:

AstraZeneca would like to inform you of the following change to the shelf life for two specific lots of FLUMIST® QUADRIVALENT that was supplied as part of a previous delivery.

Summary

- The expiry date for lots TH2989 and TH2989B have been updated following routine stability testing. *Please note this applies only to lots TH2989 and TH2989B*

- **FLUMIST® QUADRIVALENT lots TH2989 and TH2989B must be used by the updated expiry dates: December 25, 2023, and January 8, 2024, respectively**

AstraZeneca reassures healthcare professionals, patients and caregivers that the quality and safety of FLUMIST QUADRIVALENT are not affected. Please ensure all relevant staff are made aware of the content of this letter.

Background

Following routine stability testing, it was identified that the expiry dates for lots TH2989 and TH2989B required updating. The FDA Center for Biologics Evaluation and Research (CBER) has been notified.

The updated expiry dates:

Lot Number	Printed Expiry Date	Updated Expiry Date
TH2989	01-Jan-2024	25-Dec-2023
TH2989B	15-Jan-2024	08-Jan-2024

Action Required

Please ensure the above lots are fully administered before the updated expiry date.
Vaccine doses past the updated expiry should be managed according to standard procedures. Except for the updated expiry date, there are no other changes made to the product information.

AstraZeneca can assure no change in effectiveness until the updated expiry date. The quality, safety and efficacy of FLUMIST QUADRIVALENT are not affected. Doses from lots TH2989 and TH2989B administered by December 25, 2023, and January 8, 2024, respectively, require no additional follow-up on your behalf.

Company Contact Point

If you have any questions about this letter or require more information about FLUMIST QUADRIVALENT, please visit our dedicated AstraZeneca Medical Information website: https://medicalinformation.astrazeneca-us.com/. Alternatively, please contact AstraZeneca Medical Information at 1-800-236-9933.

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

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.

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

Company Contact Point

If you have any questions about this letter or require more information about FLUMIST QUADRIVALENT, please visit our dedicated AstraZeneca Medical Information website: https://medicalinformation.astrazeneca-us.com/. Alternatively, please contact AstraZeneca Medical Information at 1-800-236-9933.

Yours Sincerely,

William Moore
Director of Quality Assurance
AstraZeneca Pharmaceuticals