Quadrivalent Inactivated Influenza Vaccine (Inactivated Split Virion) (QIIV)
FLULAVAL® TETRA Supplier: GlaxoSmithKline Inc.

INDICATIONS:

- See 2024/25 Seasonal Influenza Vaccine Eligibility
- **Intended for use in eligible individuals 6 months of age and older, including those with contraindications to LAIV-Q.**

The vaccine is not approved for use in those less than 6 months of age.

DOSES AND SCHEDULE:

Children 6 months-8 years of age (inclusive): 1 or 2 doses given as 0.5 mL **IM**.

Children under 9 years of age who have not previously received any seasonal influenza vaccine require **2 doses** given 4 weeks apart. If the child has received 1 or more doses in any previous season, only a single dose is required. For children requiring 2 doses within the season, it is preferable to use the same vaccine for both doses. However, if the vaccine used for the first dose is not available or unknown, any other age-appropriate vaccine may be used for the second dose.

Children and Adolescents 9-17 years of age (inclusive): 1 dose given as 0.5 mL **IM**.

Adults 18 years of age and older: 1 dose given as 0.5 mL **IM**.

ADMINISTRATION:

Discard multi-dose vials 28 days after first entry.

BOOSTER DOSES AND RE-IMMUNIZATION:

Annually.

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine or to any component of FLULAVAL® TETRA.
2. History of Guillain-Barré syndrome (GBS) within 8 weeks of receipt of a previous dose of influenza vaccine without another cause being identified.

PRODUCT COMPONENTS:

Potential allergens: egg protein, polysorbate 80, thimerosal (in multi-dose presentation only at 50 µg per 0.5 mL dose; 0.01% w/v) (See SPECIAL CONSIDERATIONS).

Other components: phosphate buffered saline, α-tocopheryl hydrogen succinate, sodium deoxycholate, ethanol, formaldehyde, sucrose.

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PRECAUTIONS:
Severe oculo-respiratory syndrome (ORS) after a previous dose of influenza vaccine. [A]

SPECIAL CONSIDERATIONS:
Egg allergic individuals (including those who have experienced anaphylaxis following egg ingestion) can be immunized with inactivated or live attenuated influenza vaccine in any setting attended by immunization service providers who are following standard vaccine administration practice. [B]

ADVERSE EVENTS [C]:
Local: pain, swelling, redness.
Systemic: myalgia, headache, fever, fatigue, arthralgia, shivering, nausea, vomiting, diarrhea, abdominal pain. Infants and toddlers may also experience irritability, loss of appetite and drowsiness. Fewer than 1 in 20 people may develop oculo-respiratory syndrome (ORS). Symptoms include red eyes, a cough, and/or sore throat and/or hoarseness.

[A] See Safety Issues Applicable to Influenza Vaccines, 2. Oculo-Respiratory Syndrome (ORS).
[B] See Safety Issues Applicable to Influenza Vaccines, 1. Egg Allergic Individuals.
[C] These occur at similar frequencies among recipients of other influenza vaccines, are of short duration and rarely interfere with activities of daily living.