Trivalent Inactivated Influenza Vaccine (Inactivated Split Virion) (TIIV) FLUZONE® Supplier: Sanofi Pasteur Limited

INDICATIONS:

- See 2025/26 Seasonal Influenza Vaccine Eligibility
- Intended for use in eligible individuals 6 months of age and older, including those with contraindications to LAIV.

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:

A multi-dose vial that has been entered and stored at +2°C to +8°C may be used up to the expiry date indicated on the vial label.

BOOSTER DOSES AND RE-IMMUNIZATION:

Annually.

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:

- History of anaphylactic reaction to a previous dose of any type of influenza vaccine or to any component of FLUZONE®.
- 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, thimerosal (in multidose presentation only at 50 μg per 0.5 mL dose; 0.01% w/v) (See SPECIAL CONSIDERATIONS).

Other components: formaldehyde, phosphate buffered saline (sodium chloride, sodium phosphate (dibasic anhydrous), sodium phosphate (monobasic anhydrous)), Triton® X-100.

1

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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:

Local: pain, swelling, redness, induration.

Systemic: myalgia, headache, fever, malaise, chills, arthralgia, nausea, vomiting, diarrhea. Infants and toddlers may also experience irritability, abnormal crying, drowsiness, loss of appetite. 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.