FluLaval TETRA
(2022-2023)

Quadrivalent Influenza Vaccine (Split Virion, Inactivated)

Abbreviated Package Insert

See Prescribing Information for complete product information

HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

FLULAVAL TETRA is a quadrivalent vaccine indicated for active immunization of adults and children from 6 months of age for the prevention of influenza disease caused by influenza virus types A and B contained in the vaccine.

The National Advisory Committee on Immunization (NACI) provides additional guidance on the use of the influenza vaccine in Canada. Please refer to published Statement on Seasonal Influenza Vaccine for the current season.

1.1 Pediatrics

Pediatrics (6 months - 17 years): Based on the data submitted and reviewed by Health Canada, the safety and efficacy of FLULAVAL TETRA in pediatric patients has been established; therefore, Health Canada has authorized an indication for pediatric use.

2 CONTRAINDICATIONS

FLULAVAL TETRA should not be administered to subjects with known history of hypersensitivity to any component of the vaccine or following a previous dose of any influenza vaccine produced in eggs. For a complete listing, see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.

3 SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

4 DOSAGE AND ADMINISTRATION

4.2 Recommended Dose and Dosage Adjustment

- FLULAVAL TETRA should be administered as a single 0.5 mL injection.
- Children 6 months to less than 9 years of age who have not previously been vaccinated against influenza should receive a second dose of 0.5 mL after an interval of at least 4 weeks.

4.4 Administration

FLULAVAL TETRA must not be administered intravenously.

Vaccination should be carried out by intramuscular injection preferably into the deltoid muscle or anterolateral thigh (depending on the muscle mass).

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Any unused product or waste material should be disposed of in accordance with local requirements. Since FLULAVAL TETRA is a split-virion, inactivated vaccine, it presents no risk of contaminating the work area during manipulation.

For the multidose vial presentation:

The vaccine presents as an opalescent translucent to off-white suspension, that may sediment slightly.

The vial should be shaken prior to each administration and inspected visually for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, discard the vaccine.

Each vaccine dose of 0.5 mL is withdrawn into a 1mL syringe for injection and administered intramuscularly. It is recommended to equip the syringe with a needle gauge not larger than 23-G.

Between uses, the multidose vial should be stored in a refrigerator (2°C - 8°C).

5 OVERDOSAGE

Insufficient data are available.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, health professionals should record the time and date of administration, quantity of administered dose (if applicable), anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date.

Table 1 - Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredients
Intramuscular	Suspension for Injection Each 0.5 mL dose contains 15 µg of influenza virus haemagglutinin/ strain for each strain listed below.	Egg proteins, ethanol, formaldehyde, phosphate buffered saline, polysorbate 80, sodium deoxycholate, α-tocopheryl hydrogen succinate, sucrose. Thimerosal preservative in the multidose vial presentation only.

Description

FLULAVAL TETRA is a quadrivalent split-virion, inactivated influenza vaccine prepared from virus grown in the allantoic cavity of embryonated hens' eggs. The virus is inactivated with ultraviolet light treatment followed by formaldehyde treatment, purified by centrifugation and disrupted with sodium deoxycholate.

This vaccine complies with the World Health Organization (WHO) recommendation (Northern Hemisphere) for the 2022-2023 season. The quadrivalent vaccine contains 2 A strains and 2 B strains.

Each 0.5 mL dose of vaccine contains 15 micrograms haemagglutinin of each of the following four influenza virus strains:

15µg HA - A/Victoria/2570/2019 (H1N1)pdm09-like virus (A/Victoria/2570/2019 IVR-215)

15µg HA - A/Darwin/9/2021 (H3N2)-like virus (A/Darwin/9/2021 IVR-228)

15µg HA - B/Phuket/3073/2013-like virus (B/Phuket/3073/2013) from the B/Yamagata/16/88 lineage

15µg HA - B/Austria/1359417/2021-like virus (B/Austria/1359417/2021 BVR-26) from the B/Victoria/2/87 lineage

The vaccine is formulated with phosphate buffered saline composed of sodium chloride, potassium chloride, disodium hydrogen phosphate heptahydrate, potassium dihydrogen phosphate and water for injection.

Each 0.5 mL dose contains, α-tocopheryl hydrogen succinate (267 µg), and polysorbate 80 (683 µg). Each 0.5 mL dose may also contain residual amounts of egg proteins (ovalbumin ≤0.3 µg), sodium deoxycholate, ethanol, formaldehyde and sucrose from the manufacturing process.

The multidose vial presentation contains thimerosal, a mercury derivative, added as a preservative. Each 0.5 mL dose contains 50 µg thimerosal (<25 µg mercury).

Multi-dose vial presentation:

5 mL vial (type I glass) containing 10 doses of 0.5 mL

Pack size of 1 vial.

The vial stopper does not contain latex.

7 WARNINGS AND PRECAUTIONS

General

FLULAVAL TETRA should under no circumstances be administered intravascularly.

It is good clinical practice to precede vaccination by a review of the medical history (especially with regards to previous vaccination and the possible occurrence of undesirable events) and a clinical examination.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

FLULAVAL TETRA is not effective against all possible strains of influenza virus. FLULAVAL TETRA is intended to provide protection against those strains of virus from which the vaccine is prepared and to closely related strains.

Febrile or acute disease

As with other vaccines, vaccination with FLULAVAL TETRA should be postponed in subjects suffering from an acute severe febrile illness. The presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

Hematologic

As with other vaccines administered intramuscularly, FLULAVAL TETRA should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to these subjects.

Immune

An adequate immune response may not be elicited in patients receiving immunosuppressive treatment or patients with immunodeficiency.

Neurologic

If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FLULAVAL TETRA should be based on the careful consideration of the potential benefits and risks.

Immunization should be delayed in a patient with an active neurologic disorder, but should be considered when the disease process has been stabilized.

Respiratory

Revaccination of individuals who have previously experienced oculo-respiratory symptoms is safe. Previously affected individuals should be encouraged to be revaccinated. The risk of recurrence of oculo-respiratory symptoms after revaccination is minimal compared to the serious threat posed by influenza. Please refer to the most current NACI recommendations regarding revaccination of subjects who experienced more severe oculo-respiratory syndrome.

Skin

Soreness and redness at the injection site may occur and may last for up to two days. Prophylactic acetaminophen may decrease the frequency of pain at the injection site.

7.1 Special Populations

7.1.1 Pregnant Women

The safety of FLULAVAL TETRA when administered to pregnant women has not been evaluated in clinical trials. A systematic literature review on inactivated influenza vaccines do not indicate an increased risk of adverse pregnancy outcomes. Animal studies with FLULAVAL TETRA do not indicate direct or indirect harmful effects with respect to reproductive and developmental toxicity. The FLULAVAL TETRA vaccine may be administered to pregnant women following an assessment of the risks and benefits.

7.1.2 Breast-feeding

The safety of FLULAVAL TETRA when administered to breast-feeding women has not been evaluated. It is unknown whether FLULAVAL TETRA is excreted in human breast milk. FLULAVAL TETRA should only be used during breast-feeding when the possible advantages outweigh the potential risks.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

In clinical trials, FLULAVAL TETRA was administered to more than 1,960 children between 6 – 35 months of age, more than 3,500 children between 3 – 17 years of age and more than 1,200 adults.

In adults, the most common (≥10%) solicited local reaction was pain (60%); the most common solicited systemic adverse events were myalgia (26%), headache (22%), fatigue (22%), and arthralgia (15%).

In children 3 to 17 years of age, the most common (≥10%) solicited local reaction was pain (65%). In children 3 to 4 years of age, the most common (≥10%) solicited systemic adverse events were irritability (26%), drowsiness (21%), and loss of appetite (17%). In children 5 to 17 years of age, the most common (≥10%) systemic adverse events were muscle aches (29%), fatigue (22%), headache (22%), arthralgia (13%), and gastrointestinal symptoms (10%).

In children 6 to 35 months of age, injection site pain was the most common (≥10%) solicited local reaction (40%). The most common solicited systemic adverse events were irritability (49%), drowsiness (37%), and loss of appetite (29%).

See Prescribing Information for complete information on clinical trails.

8.5 Post-Market Adverse Reactions

The following adverse reactions have been identified during post approval use of FLULAVAL TETRA or FLULAVAL (trivalent influenza vaccine). Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

Blood and Lymphatic System Disorders
Lymphadenopathy.

Eye Disorders
Eye pain, photophobia.

Gastrointestinal Disorders
Dysphagia, vomiting.

General Disorders and Administration Site Conditions
Chest pain, injection site inflammation, asthenia, injection site rash, influenza-like symptoms, abnormal gait, injection site bruising, injection site sterile abscess.

Immune System Disorders
Allergic reactions including anaphylaxis, angioedema.

Infections and Infestations
Rhinitis, laryngitis, cellulitis.

Musculoskeletal and Connective Tissue Disorders
Muscle weakness, arthritis.

Nervous System Disorders
Dizziness, paresthesia, hypoesthesia, hypokinesia, tremor, somnolence, syncope, Guillain-Barré syndrome, convulsions/seizures, facial or cranial nerve paralysis, encephalopathy, limb paralysis.

Psychiatric Disorders
Insomnia.

Respiratory, Thoracic, and Mediastinal Disorders
Dyspnea, dysphonia, bronchospasm, throat tightness.

Skin and Subcutaneous Tissue Disorders
Urticaria, localized or generalized rash, pruritus, sweating.

Vascular Disorders
Flushing, pallor.

9 DRUG INTERACTIONS

9.3 Drug-Behavioural Interactions

The vaccine is unlikely to produce an effect on the ability to drive and use machines.

9.4 Drug-Drug Interactions

If FLULAVAL TETRA is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites.

9.7 Drug-Laboratory Test Interactions

False positive ELISA serologic tests for HIV-1, Hepatitis C, and especially HTLV-1 may occur following influenza vaccination. These transient false-positive results may be due to cross-reactive IgM elicited by the vaccine. For this reason, a definitive diagnosis of HIV-1, Hepatitis C, or HTLV-1 infection requires a positive result from a virus-specific confirmatory test (e.g., Western Blot or immunoblot).

11 STORAGE, STABILITY AND DISPOSAL

Store in a refrigerator (2°C – 8°C).

Do not freeze.

Store in the original package in order to protect from light.

The vaccine is stable for 12 months.

Once entered, the multidose vial should be discarded within 28 days.

12 SPECIAL HANDLING INSTRUCTIONS

Any unused product or waste material should be disposed of in accordance with local requirements.

The full product monograph, prepared for health professionals can be found at www.gsk.ca or by contacting the sponsor, GlaxoSmithKline Inc.

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