# FLUZONE® High-Dose Quadrivalent

**High-Dose Quadrivalent Influenza Virus Vaccine - Types A and B (Split Virion)**

Suspension for Intramuscular Injection

**Abbreviated Package Insert**

**See Product Monograph for complete product information**

## INDICATIONS

- FLUZONE® High-Dose Quadrivalent vaccine is indicated for active immunization against influenza caused by the specific strains of influenza virus contained in the vaccine in adults 65 years of age and older.
- The National Advisory Committee on Immunization (NACI) provides additional guidance on the use of the influenza vaccine in Canada. Please refer to the published Statement on Seasonal Influenza Vaccine for the current season.

### Pediatrics

Pediatrics (<18 years of age): Based on the data submitted and reviewed by Health Canada, the safety and efficacy of FLUZONE® High-Dose Quadrivalent administration in children less than 18 years of age have not been established; therefore, Health Canada has not authorized an indication for pediatric use.

### Geriatrics

Geriatrics (≥65 years of age): FLUZONE® High-Dose Quadrivalent vaccine is indicated for active immunization for the prevention of influenza in adults 65 years of age and older.

## CONTRAINDICATIONS

FLUZONE® High-Dose Quadrivalent is contraindicated in anyone with a known systemic hypersensitivity reaction after previous administration of any influenza vaccine or to any component of the vaccine (e.g. eggs or egg products). For a complete listing, see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.

## DOSAGE AND ADMINISTRATION

### Recommended Dose and Dosage Adjustment

The recommended dosage of FLUZONE® High-Dose Quadrivalent is 1 dose of 0.7 mL, annually, in persons 65 years of age and older.

Fractional doses (doses <0.7 mL) should not be given. The safety and efficacy of fractional doses have not been determined.

Health Canada has not authorized an indication for pediatric use in children less than 18 years of age. (See 7 WARNINGS AND PRECAUTIONS, 7.1 Special Populations, 7.1.3 Pediatrics) or in adults less than 65 years of age.

### Administration

**Administration Route Related Precautions:** Do not administer by intravascular injection; ensure that the needle does not penetrate a blood vessel.

FLUZONE® High-Dose Quadrivalent should not be administered into the buttocks.

Inspect for extraneous particulate matter and/or discolouration before use. If either of these conditions exist, the product should not be administered.

Administer the vaccine **intramuscularly**. The preferred site is the deltoid muscle. The vaccine should not be injected into the gluteal region or into areas where there may be a major nerve trunk. For needle length, refer to national recommendations.

Do not administer this product intravenously.

**Shake the prefilled syringe well** to uniformly distribute the suspension before administering the dose.

Aseptic technique must be used. Use a separate, sterile needle, for each individual patient to prevent disease transmission. Needles should not be recapped and should be disposed of according to biohazard waste guidelines.

Give the patient a permanent personal immunization record. In addition, to ensure traceability for patient immunization record keeping as well as safety monitoring, it is essential that the physician or nurse record the immunization history in the permanent medical record of each patient. This permanent office record should contain the brand name and generic name of the vaccine, date and time given, anatomical site and route of administration, quantity of administered dose, lot number and expiry date.

### Missed Dose

Not applicable for this vaccine.

## OVERDOSAGE

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

## 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 | **Dosage Form:** Suspension for injection<br>**Active Ingredients:** Each 0.7 mL dose contains 60 µg Hemagglutinin (HA) of each strain listed below | Octylphenol ethoxylate (Triton® X-100), sodium phosphate buffered isotonic sodium chloride solution. Traces of formaldehyde and ovalbumin |

FLUZONE® High-Dose Quadrivalent [Influenza Virus Vaccine Quadrivalent Types A and B (Split Virion)] is a sterile aqueous suspension of inactivated influenza virus for intramuscular injection. FLUZONE® High-Dose Quadrivalent contains 4 strains of influenza propagated in embryonated chicken eggs. The virus-containing fluid is harvested and inactivated with formaldehyde. Influenza virus is concentrated and purified in a linear sucrose density gradient solution using a continuous flow centrifuge. The virus is then chemically disrupted using a non-ionic surfactant, octylphenol ethoxylate (octoxinol-9, Triton® X-100) producing a "split-virus." The split-virus is then further purified by diafiltration against phosphate-buffered chloride saline. FLUZONE® High-Dose Quadrivalent is formulated to contain 240 micrograms (µg) hemagglutinin per 0.7 mL dose in the recommended ratio of 60 µg HA of each of the four influenza strains (A/H3N2, A/H1N1, B/Yamagata like, and B/Victoria like).

Antibiotics are not used in the manufacture of FLUZONE® High-Dose Quadrivalent.

There is no thimerosal used in the manufacturing process of FLUZONE® High-Dose Quadrivalent.

FLUZONE® High-Dose Quadrivalent is supplied as a sterile aqueous suspension for injection in a prefilled syringe. After shaking the syringe well, FLUZONE® High-Dose Quadrivalent is a colorless opalescent liquid.

This vaccine complies with the World Health Organization (WHO) recommendation (Northern Hemisphere) for the 2022-2023 season. For the 2022-2023 season FLUZONE® High-Dose Quadrivalent contains the following:

**Active Ingredients:**

Each 0.7 mL dose contains 60 µg HA of each strain listed below:

- A/Victoria/2570/2019 (H1N1)pdm09 - like strain (A/Victoria/2570/2019, IVR-215)
- A/Darwin/9/2021 (H3N2) - like strain (A/Darwin/9/2021, SAN-010)
- B/Austria/1359417/2021 - like strain (B/Michigan/01/2021, wild type)
- B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, wild type)

Other Ingredients:

0.7 mL dose: ≤ 350 µg octylphenol ethoxylate (Triton® X-100), ≤ 200 µg/mL formaldehyde and up to 0.7 mL sodium phosphate buffered isotonic sodium chloride solution.

Each dose may contain traces of ovalbumin. Antibiotics and thimerosal are not used in the manufacture of FLUZONE® High-Dose Quadrivalent.

### Packaging

FLUZONE® High-Dose Quadrivalent is supplied in single dose prefilled syringes.

The syringes are made of Type 1 glass. The container closure system for FLUZONE® High-Dose Quadrivalent does not contain latex (natural rubber). FLUZONE® High-Dose Quadrivalent is considered safe for use in persons with latex allergies.

FLUZONE® High-Dose Quadrivalent is available in packages of:

5 x 0.7 mL (single dose) syringes without attached needle;

10 x 0.7 mL (single dose) syringes without attached needle.

Not all pack sizes may be marketed.

## WARNINGS AND PRECAUTIONS

### General

Before administration of FLUZONE® High-Dose Quadrivalent, health-care providers should inform the recipient or guardian of the recipient of the benefits and risks of immunization, inquire about the recent health status of the recipient, review the recipient's history concerning possible hypersensitivity to the vaccine or similar vaccines, previous immunization history, the presence of any contraindications to immunization and comply with any local requirements regarding information to be provided to the recipient/guardian before immunization.

Syncope can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent falling and injury and to manage syncope.

As with any vaccine, vaccination with FLUZONE® High-Dose Quadrivalent may not protect 100% of recipients against influenza illness.

Influenza virus is unpredictable in that significant antigenic changes may occur from time to time. At this time, current influenza virus vaccines are not effective against all possible influenza strains. Protection is highest against those strains of virus from which the vaccine is prepared or against closely related strains.

**Febrile or Acute Disease:** Vaccination should be postponed in case of a moderate or severe acute disease with or without fever; however, a mild disease should not usually be a reason to postpone vaccination.

### Hematologic

Because any intramuscular injection can cause an injection site hematoma in persons with any bleeding disorders, such as haemophilia or thrombocytopenia, or in persons on anticoagulant therapy, intramuscular injections with FLUZONE® High-Dose Quadrivalent should not be administered to such persons unless the potential benefits outweigh the risk of administration. If the decision is made to administer any product by intramuscular injection to such persons, it should be given with caution, with steps taken to avoid the risk of hematoma formation following injection.

The Canadian Immunization Guide has recommendations for giving vaccinations to persons with bleeding disorders.

### Immune

Prior to any vaccination, all known precautions should be taken to prevent hypersensitivity reactions. Epinephrine hydrochloride solution (1:1,000) and other appropriate agents used for the control of immediate allergic reactions must be available to treat unexpected reactions, such as anaphylaxis. 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. Health-care providers should be familiar with current recommendations for the initial management of anaphylaxis in non-hospital settings including proper airway management. For instructions on recognition and treatment of anaphylactic reactions see the current edition of the Canadian Immunization Guide or visit the Health Canada website.

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**FLUZONE® High-Dose Quadrivalent**
**Influenza Virus Vaccine Quadrivalent**
**Types A and B (Split Virion)**

As each dose may contain traces of formaldehyde, ovalbumin and octylphenol ethoxylate, which are used during vaccine production, caution should be exercised when the vaccine is administered to persons with hypersensitivity to one of these substances. See 2 CONTRAINDICATIONS.

The immunogenicity of FLUZONE® High-Dose Quadrivalent may be reduced by immunosuppressive treatment or in individuals with immune deficiency syndromes. In such cases it is recommended to postpone the vaccination until after the immunosuppressive treatment or resolution of the immunosuppressive condition, if feasible. Nevertheless, as recommended by NACI, the possibility of lower efficacy should not prevent immunization in those at high risk of influenza-associated morbidity, since some protection is still likely to occur.

### Neurologic

If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of any previous influenza vaccination, the decision to give FLUZONE® High-Dose Quadrivalent should be based on careful consideration of the potential benefits and risks. See 8 ADVERSE REACTIONS.

### Skin

Local reactions at injection site such as pain, erythema, swelling, induration and bruising may occur. See 8 ADVERSE REACTIONS.

### Special Populations

#### Pregnant Women

Animal reproductive studies have not been conducted with FLUZONE® High-Dose Quadrivalent. It is also not known whether FLUZONE® High-Dose Quadrivalent can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. FLUZONE® High-Dose Quadrivalent is indicated for persons 65 years of age and older.

#### Breast-feeding

It is not known whether FLUZONE® High-Dose Quadrivalent is excreted in human milk. FLUZONE® High-Dose Quadrivalent is indicated for persons 65 years of age and older.

#### Pediatrics

Pediatrics (<18 years of age): Based on the data submitted and reviewed by Health Canada, the safety and efficacy of FLUZONE® High-Dose Quadrivalent administration in children less than 18 years of age have not been established; therefore, Health Canada has not authorized an indication for paediatric use.

#### Geriatrics

Geriatrics (≥65 years of age): FLUZONE® High-Dose Quadrivalent is indicated for persons 65 years of age and older.

## ADVERSE REACTIONS

For adverse events information derived from clinical trials and worldwide post-marketing experience, **please refer to the complete Product Monograph.**

Health professionals should report any adverse occurrences temporally related to the administration of the product in accordance with local requirements. (See PATIENT MEDICATION INFORMATION, Reporting Side Effects for Vaccines).

## DRUG INTERACTIONS

For information on Drug Interactions, please refer to the complete Product Monograph.

## CLINICAL PHARMACOLOGY

For Mechanism of Action, Pharmacodynamics and Duration of Effect, please refer to the complete Product Monograph.

## STORAGE, STABILITY AND DISPOSAL

Store at 2° to 8°C (i.e. in a refrigerator). **Do not freeze.** Discard product if exposed to freezing.

## SPECIAL HANDLING INSTRUCTIONS

Do not use after the expiration date shown on the label.

Vaccine Information Service: 1-888-621-1146

Full product monograph available on request or visit us at www.sanofi.ca

Product information as of April 2022.

Fabricated by: **Sanofi Pasteur Inc.,** Swiftwater, PA 18370 USA

Manufactured and Distributed by: **Sanofi Pasteur Limited** , Toronto, Ontario, Canada

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