For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Abridged Prescribing Information

QUADRIVALENT Inactivated Influenza vaccine (Split virion) I.P.

FluQuadri®

The single-dose, pre-filled syringe (0.25 mL and 0.5 mL) are manufactured and formulated without thimerosal or any other preservative. The amounts of HA and other ingredients per dose of vaccine are listed in Table 1.

Table 1: FluQuadri® Ingredients

Ingredient	Quantity (per dose)	
	FluQuadri® 0.25 mL Dose	FluQuadri® 0.5 mL Dose
Active Substance: Split influenza virus, inactivated strains[a]:	30 mcg HA total	60 mcg HA total
A (H1N1)*	7.5 mcg HA	15 mcg HA
A (H3N2)*	7.5 mcg HA	15 mcg HA
B/(Victoria lineage)*	7.5 mcg HA	15 mcg HA
B/(Yamagata lineage)*	7.5 mcg HA	15 mcg HA
Other		
Sodium phosphate-buffered isotonic sodium chloride solution	QS[b] to appropriate volume	QS[b] to appropriate volume
Formaldehyde	≤50 mcg	≤100 mcg
Octylphenol ethoxylate (Triton® X-100)	≤125 mcg	≤250 mcg
Preservative	-	-

*Will vary year to year based on the strains slected as per WHO recommendations for each NH and SH Influenza season.

THERAPEUTIC INDICATIONS

FluQuadri® is an inactivated quadrivalent influenza vaccine indicated for the prevention of influenza disease caused by influenza types A and B viruses contained in the vaccine. FluQuadri® is approved for use in persons 6 months of age and older.

DOSAGE AND ADMINISTRATION

- **For intramuscular use only**

Dose and Schedule

Table 2: Dose and Schedule for FluQuadri:

Age	Dose	Schedule
6 months through 35 months	One or two doses[a] , 0.25 mL each	If 2 doses, administer at least 4 weeks apart
3- 8 years	One or two doses[a], 0.5 mL each	If 2 doses, administer at least 4 weeks apart
9 years and older	One dose, 0.5 mL	-

[a] 1 or 2 doses depends on vaccination history as per Advisory Committee on Immunization Practices annual recommendations on prevention and control of influenza with vaccines.

Administration Inspect FluQuadri® visually for particulate matter and/or discoloration prior to administration. The preferred sites for intramuscular injection are the anterolateral aspect of the thigh in infants 6 months through 11 months of age, the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in persons 12 months through 35 months of age, or the deltoid muscle in persons ≥36 months of age The vaccine should not be injected into the gluteal area or areas where there may be a major nerve trunk.Do not administer this product intravenously, intradermally, or subcutaneously. FluQuadri® vaccine should not be combined through reconstitution or mixed with any other vaccine.

DOSAGE FORMS AND STRENGTHS FluQuadri® is a suspension for injection.Prefilled single-dose syringe (pink syringe plunger rod), 0.25 mL, for persons 6 months through 35 months of age, Prefilled single-dose syringe (clear syringe plunger rod), 0.5 mL, for persons 36 months of age and older.

SAFETY RELATED INFORMATION

CONTRAINDICATIONS

A severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine , including egg protein, or to a previous dose of any influenza vaccine is a contraindication to administration of FluQuadri®.

Pregnancy It is also not known whether FluQuadri® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. FluQuadri® should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether FluQuadri® is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when FluQuadri® is administered to a nursing woman.

WARNINGS AND PRECAUTIONS

Guillain-Barré Syndrome

Recurrence of Guillain-Barré syndrome (GBS) has been temporally associated with administration of influenza vaccine.

Preventing and Managing Allergic Reactions Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

Altered Immunocompetence If FluQuadri® is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the expected immune response may not be obtained.

Limitations of Vaccine Effectiveness Vaccination with FluQuadri® may not protect all recipients.

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse event rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trial of another vaccine, and may not reflect the rates observed in practice.

For full prescribing information, please contact Sanofi Pasteur India Pvt. Ltd., Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072 – India

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