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

Abridged Prescribing Information

Inactivated Influenza Vaccine (Split Virion) I.P.

NH-2025-2026
Vaxigrip®

QUALITATIVE & QUANTITATIVE COMPOSITION:

Each dose of 0.5ml contains-
A/Victoria/4897/2022 (H1N1) pdm09-like strain*……15mcg hemagglutinin
A/Croatia/10136RV/2023 (H3N2)-like strain*……..15mcg hemagglutinin
B/Austria/1359417/2021(B/Victoria lineage)-like strain*…….15mcg hemagglutinin
Phosphate buffered saline (PBS) solution…q.s.
*propagated on hens eggs

Recommended composition of influenza virus vaccines for use in the 2025-2026 Northern Hemisphere influenza season.

Inactive ingredients: Phosphate buffered saline solution q.s 0.5 ml: Sodium chloride 8g/L Potassium chloride 0.2g/L, Disodium phosphate dihydrate 1.15g/L, Potassium dihydrogen phosphate 0.2 g/L, Water for injections q.s.
Inactivated with formaldehyde.

THERAPEUTIC INDICATIONS:

Prophylaxis of influenza.

- Active immunization of adults, including pregnant women, and children from 6 months of age and older.
- Passive protection of infant(s) from birth to less than 6 months of age following vaccination of pregnant women.

The use of VAXIGRIP should be based on official recommendations.

DOSAGE AND ADMINISTRATION:

Posology:
Adults: one dose of 0.5 ml.

Paediatric population
- Children from 6 months to 17 years of age: one dose of 0.5 mL.

For children less than 9 years of age who have not previously been vaccinated, a second dose of 0.5 ml should be given after an interval of at least 4 weeks.
- Infants less than 6 months of age: the safety and efficacy of Vaxigrip administration (active immunization) have not been established. No data are available.

Regarding passive protection: one 0.5 mL dose given to pregnant women may protect infants from birth to close to 6 months of age (refer full prescribing information)

Method of administration:

The preferred route of administration for this vaccine is intramuscular although it can also be given subcutaneously.

The preferred sites for intramuscular injection are the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in children 6 months through 35 months of age, or the deltoid muscle in children from 36 months of age and adults.

Precautions to be taken before handling or administering the medicinal product

DOSAGE FORMS AND STRENGTHS:

Trivalent suspension for injection in a 0.5ml pre-filled syringe with attached needle

SAFETY RELATED INFORMATION

CONTRAINDICATIONS: Hypersensitivity to the active substances, to any of the excipients or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde and octoxinol-9.

WARNINGS AND PRECAUTIONS:

Hypersensitivity

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.

Concurrent illness:

Vaccination should be postponed in patients with acute febrile illness until the fever is resolved.

Thrombocytopenia and coagulation disorders:

As with other vaccines administered intramuscularly, the vaccine should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

Syncope:

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent injury from fainting and manage syncopal reactions.

Precautions for use:

Vaxigrip should under no circumstances be administered intravascularly.

USE IN SPECIFIC POPULATIONS:

Pregnancy

Pregnant women are at high risk of influenza complications, including premature labor and delivery, hospitalization, and death: pregnant women should receive an influenza vaccine. Vaxigrip can be used in all stages of pregnancy.

Nursing Mothers
Vaxigrip may be used during breastfeeding.

ADVERSE REACTIONS:
The safety profile of Vaxigrip is based on data from 46 clinical studies in which approximately 17,900 participants from 6 months of age received Vaxigrip or Vaxigrip Tetra, and data from post-marketing surveillance. Most of adverse reactions usually occurred within the first 3 days after vaccination and resolved spontaneously within 1 to 3 days of their onset. The intensity of most these reactions was mild to moderate. The most frequently reported undesirable effect after vaccination, in all populations including the whole group of children from 6 to 35 months of age, was injection site pain. The other most frequently reported adverse reactions after vaccination were In adults: headache, myalgia and malaise; In elderly: headache and myalgia; In children from 9 to 17 years of age: myalgia headache, malaise, shivering, injection site erythema and injection site swelling: In children from 3 to 8 years of age: malaise, injection site erythema, myalgia, headache, injection site swelling, injection site induration, shivering: In all children from 6 to 35 months of age: fever and injection site erythema: In children 6 months to 23 months of age: irritability, crying abnormal, appetite lost, drowsiness and vomiting: In children from 24 to 35 months of age: malaise, myalgia, headache.

For full prescribing information, refer to the company website www.sanofi.in

Updated on: 2 Sept 2025

Ref: Based on WHO recommendations for 2025/2026 Northern Hemisphere season and EU SmPC dated Nov 2024.