Quadrivalent influenza vaccine (split virion, inactivated) [VaxigripTetra®]
Abridged Product Information
2023 Flu Season

Quadrivalent Seasonal Influenza Vaccine (Split Virion, Inactivated)

VaxigripTetra®

Product: Quadrivalent influenza vaccine (split virion, inactivated) [VaxigripTetra®]
Strength: 0.5 mL Suspension for Intramuscular or Subcutaneous Injection in pre-filled syringe
Presentation: 0.5 mL in 1 mL Type 1 pre-filled glass syringe with or without attached needle (Box of 1, 10, or 20)
I: *Quadrivalent influenza vaccine (split virion, inactivated)* –For the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine for: the active immunization of individuals from the age of 6 months and older, including pregnant women, and the passive protection of infants less than 6 months of age born to women vaccinated during pregnancy.
C:Hypersensitivity to the active substances or to any of the excipients listed or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde, and octoxinol-9. Postponement of the vaccination shall be done when there is a presence of an illness with a high or moderate temperature, or an acute illness.
W/P: Should be given with caution to individuals with a poor immune response, and bleeding problems or bruises easily. The immunological response may decrease in case of immunosuppressant treatment such as corticosteroids, cytotoxic drugs, or radiotherapy. Syncope (fainting)can occur following or even before any vaccination as a psychogenic response to the needle injection thus procedures should be in place to prevent injury. This vaccine may not fully protect all persons who are vaccinated. Regarding passive protection, not all infants less than 6 months of age born to women during pregnancy may be protected. For pregnant, or breast-feeding, consult your healthcare provider before receiving the vaccine. This can be used in all stages of pregnancy, and during breast feeding. This vaccine has no or negligible influence on the ability to drive and use machines.
Interactions: Separate injection sites and separate needles should be used in case of concomitant administration. The immunological response may be reduced if the patient is undergoing immunosuppressant treatment. Transient false positive results in serology tests using the ELISA method to detect antibodies have been observed due to the IgM response by the vaccine.
AE: Allergic reactions, headache, muscle pain, malaise, swelling or pain at the injection site, fever, shivering, loss of appetite
PK/ PD: VaxigripTetra® provides immunization against four influenza virus strains (two A subtypes and two B types) contained in the vaccine. It induces humoral antibodies against the haemagglutinins within 2 to 3 weeks. These antibodies neutralize influenza viruses. Since influenza viruses constantly evolve, the virus strains selected in the vaccine are reviewed annually by the WHO. Based on clinical experience with the trivalent vaccine, annual influenza vaccine is recommended given the duration of immunity provided by the vaccine and because circulating strains of influenza virus change from year to year. Clinical studies performed in adults from 18 to 60 years of age, in elderly over 60 years, in children from 3 to 8 years of age and from 6 to 35 months assessed VaxigripTetra® immune response for HAI Geometric mean antibody tire (GMT) at Day 21 (for adults) and at Day 28 (for children), HAI seroconversion rate, and HAI GMTR. VaxigripTetra® induced a significant immune response against the 4 influenza strains contained in the vaccine. Non-clinical data revealed no special hazard for humans based on conventional studies of repeat dose and local toxicity, reproductive and developmental toxicity and safety pharmacology studies.

Date of Revision: June 2022
Reference: 2023 Quadrivalent influenza vaccine (split virion, inactivated) [VaxigripTetra®]. Philippines Prescribing Information.

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MAT-PH-2300381 | VER 1.0 | DA 03-2023 | DM 03-2023