Rx VaxiFlu™-4

0.5 ml single dose PFS of Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent)

FOURFRONT OF PROTECTION EVERY YEAR

ABRIDGED PRODUCT INFORMATION:

COMPOSITION: Each dose of 0.5 ml contains: A/Victoria/4897/2022 (H1N1) pdm09 – like virus ≥ 15 µg HA (hemagglutinin), A/Thailand/8/2022 (H3N2)-like virus; ≥ 15 µg HA B/Austria/1359417/2021 (B/Victoria lineage) – like virus ≥ 15 µg HA B/Phuket/3073/2013 (B/Yamagata lineage) – like virus ≥ 15 µg HA propagated in fertilized hen's eggs from healthy chicken flocks & inactivated by beta propiolactone. **DESCRIPTION:** VaxiFlu-4 (Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent)) is a sterile, slightly opalescent liquid for injection. The vaccine complies with the World Health Organization (WHO) recommendation SH (Southern Hemisphere) for 2024. **MECHANISM OF ACTION:** VAXIFLU-4 provides active immunization against the four influenza virus strains (two A subtypes and two B types) contained in the vaccine. VAXIFLU-4 induces humoral antibodies against the haemagglutinins. These antibodies neutralize influenza viruses. Specific levels of hemagglutination-inhibition (HI) antibody titer post-vaccination with inactivated influenza virus vaccines have not been correlated with protection from influenza illness but the HI antibody titers have been used as a measure of vaccine activity. In some human challenge studies, HI antibody titres of ≥1:40 have been associated with protection from influenza illness in up to 50% of subjects. **INDICATIONS:** VaxiFlu-4 is indicated in Children from 6 months to 17 years and adults ≥ 18 years of age for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. **DOSAGE AND ADMINISTRATION:** The recommended dose of Vaxiflu-4 for children above 6 months through 35 months,3 years through 8 years is 0.5ml, single or two doses, a month apart. The recommended dose of Vaxiflu-4 for children above 9 years of age is 0.5ml, single dose. For adults (≥ 18 years of age) the recommended dose is 0.5ml single dose. The preferred site for intramuscular injection is the deltoid muscle of the upper arm. Do not inject in the gluteal area or areas where there may be a major nerve trunk. **CONTRAINDICATIONS:** VaxiFlu-4 is contraindicated in person with history of severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or following a previous dose of any influenza vaccine. Immunization shall be postponed in patients with acute febrile illness. **SPECIAL WARNINGS AND PRECAUTIONS:** Not to be administered iv. In rare cases anaphylactic shock may occur for such emergency 1:1000 adrenaline injection should be kept ready to be injected im or sc. If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give VaxiFlu-4 should be based on careful consideration of the potential benefits and risks. Syncope (fainting) can occur in association with administration of injectable vaccines, including VaxiFlu-4. Syncope can be accompanied by visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope. As with other intramuscular injections, VaxiFlu-4 should be given with caution in individuals with bleeding disorders such as hemophilia or on anticoagulant therapy, to avoid the risk of hematoma following the injection. Vaccination with VaxiFlu-4 may not protect all susceptible individuals. Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1, have been observed. The Western Blot technique disproves the results. The transient false positive reactions could be due to the IgM response by the vaccine. **USE IN PREGNANCY AND LACTATION:** There are no adequate and well-controlled studies in pregnant women. Data from worldwide use of influenza vaccine during pregnancy do not indicate any adverse fetal or maternal outcomes attributable. **INTERACTION with other medicinal products and other forms of interaction:** If VaxiFlu-4 is administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the immune response may be lower than in immunocompetent persons. VaxiFlu-4 must not be mixed with any other vaccine in the same syringe. If VaxiFlu-4 is to be given at the same time as another injectable vaccine. The vaccines should always be administered at different injection sites **UNDESIRED EFFECTS:** Adverse reactions that have been observed during clinical trial with Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent) include (irrespective of causal association): injection site pain, headache, fever, cold, vertigo, nausea, body ache, myalgia, fatigue and vomiting. **STORAGE CONDITION:** Store between 2-8 °C. Do not freeze. Discard if vaccine is frozen. Protect from Light, shake well before use. **PRESENTATION:** a) 0.5 ml Single-dose PFS.

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

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