Typhoid Polysaccharide Vaccine (TyphimVi)
Abridged Product Information

Polysaccharide Typhoid Vaccine

TYPHIM Vi®

Product: Typhoid Polysaccharide Vaccine (Typhim Vi)
Strength: 0.5 mL Suspension for Injection for Intramuscular or Subcutaneous Injection
Presentation: 0.5 mL Type 1 pre-filled glass syringe (Box of 1's)
I: Poliomyelitis vaccine (inactivated) – Indicated for the protection of adults and children over 2 years of age against typhoid fever. This vaccine is intended for travelers to endemic areas (areas where the disease is present and affects a large part of the population), migrants, healthcare professionals and military personnel.
C: Hypersensitivity to the active substance, to any of the excipients, to formaldehyde or to casein which may be present in traces owing to their use during the manufacturing process. Vaccination should be postponed in case of acute febrile disease.
W/P: Syncope can occur following, or even before, any vaccination as a psychogenic response to the needle injection, especially in adolescents. This may be accompanied by several neurological signs such as transient sight disorders, paraesthesia and tonic-clonic limb movements during the recovery phase. It is important that procedures be in place to avoid any injury from faints. This vaccine protects against the risks of infection by *Salmonella typhi* but not against *Salmonella paratyphi* A or B or non-typhoidal salmonella. The immunogenicity of TYPHIM Vi may be reduced by immunosuppressive treatment or immunodeficiency. It is then recommended to wait until the end of the treatment or disease before vaccinating. Nevertheless, vaccination of subjects with chronic immunodeficiency, such as HIV infection, is recommended even if the immune response may be limited. Injection must be performed via the subcutaneous route in subjects with thrombocytopenia or bleeding disorders. As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available, in the event of a rare anaphylactic reaction following administration of the vaccine. This vaccine is not indicated in children under 2 years of age because of the risk of insufficient antibody response.
Interactions: This vaccine can be associated with other common vaccines (hepatitis A, yellow fever, diphtheria, tetanus, poliomyelitis, rabies, meningitis A + C and hepatitis B) during the same vaccination session, using separate injection sites.
AE: Redness, Swelling and Pain on the injection site, Headache, Myalgia, Generally feeling unwell, Fatigue, Fever
PK/ PD: Typhim Vi is prepared from purified Vi capsular polysaccharides of Salmonella typhi. Immunity appears between 1 to 3 weeks after the injection. Protection lasts around 3 years. A double-blind, randomized, controlled efficacy clinical study was conducted in a highly endemic area in Nepal, in children and adults from 5 to 44 years. Compared with the control group, vaccine efficacy conferred by a single dose of vaccine Typhim Vi was 74% against blood culture-confirmed cases of typhoid fever throughout the 20 months of active surveillance. Seroconversion rate, defined as 4-fold rise of anti-Vi antibody levels, was collected in 19 clinical trials. These trials were conducted in endemic and non-endemic areas in adults and children from 2 years of age representing a total of 2,137 evaluable subjects. In the adult population, the seroconversion rate ranged from 62.5% to 100% three to four weeks after a single injection, with similar magnitude of anti-Vi immune response in non-endemic areas compared to endemic areas. In a double-blind, randomized, controlled efficacy clinical study conducted in a highly endemic area in South Africa, subjects from 5 to 15 years of age received Typhim Vi. Compared with the control group, vaccine efficacy conferred by a single dose of vaccine TYPHIM Vi was 55% against blood culture- confirmed cases of typhoid fever during a 3-year follow-up. Immunogenicity was assessed in both endemic and non-endemic areas in paediatric population aged from 2 to 17 years. In 9 clinical studies including 733 evaluable children, three to four weeks after a single injection of TYPHIM Vi, the seroconversion rate ranged from 67% to 100%, with a magnitude of anti-Vi immune response like that documented in adult.

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