Diphtheria, Tetanus, Pertussis (acellular, component) and Poliomyelitis (inactivated) Vaccine (adsorbed)

Tetraxim
4-IN-1 SCHOOL ENTRY VACCINE

Product: Diphtheria, tetanus, pertussis (acellular, component), and poliomyelitis (inactivated) vaccine adsorbed (Tetraxim)
Strength: 0.5 mL Suspension for Injection for Intramuscular Injection
Presentation: 0.5 mL Type 1 single-dose prefilled syringe with or without needle (Box of 1, or 10)
I: Diphtheria, tetanus, pertussis (acellular, component), and poliomyelitis (inactivated) vaccine adsorbed – Indicated in children from the age of 2 months to protect against diphtheria, tetanus, pertussis, and poliomyelitis.
C: Known systemic hypersensitivity reaction to any of the vaccine components, to glutaraldehyde, neomycin, streptomycin, or polymyxin B, or to a pertussis vaccine. Sufferingfrom evolving encephalopathy (cerebral lesions) or encephalopathy within 7 days of a previous dose of a pertussis vaccine. Vaccination should be postponed in cases of an acute or febrile disease.
W/P: It is recommended to wait until the end of the treatment before vaccination if the patient is treated with corticosteroids, cytotoxic drugs, radiotherapy or other drugs that may weaken his/her immune system. If Guillain-Barré syndrome or brachial neuritis occurred following receipt of a prior vaccine containing tetanus toxoid, the decision to givefurther vaccine should be evaluated. Precaution is taken if your child has blood or clotting disorders, or febrile convulsions. The decision to give further doses of pertussis- containing vaccine should be evaluated if the child experiences: fever of 40°C or above, collapse or shock-like state with hypotonic hyporesponsive episode, persistent inconsolable crying, or convulsions with or without fever all within 48 hours after a previous administration of a vaccine.
Interactions: For primary vaccination and for the 1st booster dose, Tetraxim may be administered by reconstituting the Haemophilus influenzae type b conjugate vaccine (Act- Hib) or administered simultaneously with it in two separate injection sites.
AE: Loss of appetite, nervousness, irritability, headache, vomiting, fever, redness, pain, or swelling at the injection site
PK/ PD: Diphtheria and tetanus toxins are detoxified using formaldehyde and then purified. The poliomyelitis vaccine is obtained from the propagation of poliomyelitis virus types 1, 2 and 3 on Vero cells, purified, then inactivated using formaldehyde. The acellular pertussis components (PT and FHA) are extracted from Bordetella pertussis cultures, then purified. The pertussis toxin (PT) is detoxified by glutaraldehyde and corresponds to the pertussis toxoid (PTxd). Immunogenicity studies have shown that all infants (100%) vaccinated with three doses of vaccine from 2 months of age developed a seroprotective antibody titre (>0.01 IU/mL) to both diphtheria and tetanus antigens. As for pertussis, one to two months after the third dose of the primary vaccination, more than 87% of infants achieved a four-fold increase in PT and FHA antibody titres. Following primary vaccination, at least 99.5% of children had seroprotective antibody titres to poliomyelitis virus types 1, 2 and 3 (≥5 as expressed by reciprocal of dilution in seroneutralisation) and were considered as protected against poliomyelitis. After the first booster dose (16-18 months), all children developed protective antibodies against diphtheria (>0.1 IU/mL), tetanus (>0.1 IU/mL) and 87.5% against poliomyelitis viruses (≥5 as expressed by reciprocal of dilution in seroneutralisation). In clinical studies with Tetraxim in people aged 4 to 13 years, booster responses against diphtheria, tetanus, poliomyelitis virus types 1, 2 and 3, and pertussis antigens were elevated and greater than seroprotective levels against diphtheria (≥0.1 IU/mL), tetanus (≥0.1 IU/mL) and poliomyelitis virus types 1, 2 and 3 (≥8 as expressed by reciprocal of dilution in seroneutralisation). Non-clinical data revealed no special hazard for humans based on conventional acute toxicity, repeat dose toxicity and local tolerance studies.

Reference: Diphtheria, tetanus, pertussis (acellular, component), and poliomyelitis (inactivated) vaccine adsorbed Tetraxim. CCDS 2022. Product Insert dated 2022.

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MAT-PH-2300633 | VER 1.0 | DA 05-2023 | DM 05-2023