Product: Diphtheria, tetanus, pertussis (acellular, multi-component), poliomyelitis (inactivated) and *Haemophilus* type b conjugate vaccine, adsorbed (Pentaxim)
Strength: 0.5 mL Powder and Suspension for Suspension for Injection for Intramuscular Injection
Presentation: 0.5 mL Type 1 prefilled glass syringe with 2 separate needles and Type 1 glass vial (Box of 1's and 10's)
I: Diphtheria, tetanus, pertussis (acellular, multi-component), poliomyelitis (inactivated) and *Haemophilus* type b conjugate vaccine, adsorbed – Indicated in children from the age of 2 months to protect against diphtheria, tetanus, whooping cough, poliomyelitis and against invasive infections caused by *Haemophilus influenzae* type b bacterium. It does not protect against infections caused by other types of *Haemophilus influenzae* or against meningitis due to other micro-organisms.
C: Known systemic hypersensitivity reaction to any of the vaccine components, to glutaraldehyde, neomycin, streptomycin, or polymyxin B, or to a pertussis vaccine. Suffering from evolving encephalopathy (cerebral lesions) or encephalopathy within 7 days of a previous dose of a pertussis vaccine. Allergic reaction after a previous injection of the same vaccine or a vaccine containing the same substances. Vaccination should be postponed in cases of an acute or febrile disease.
W/P: 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. If Guillain-Barré syndrome or brachial plexus neuropathy occurred following receipt of a prior vaccine containing tetanus toxoid, the decision to give further vaccine should be evaluated. Administration into two separate injection sites on different days should be done if the patient presents swelling in lower limbs following injection of a *Haemophilus influenzae* type-b containing vaccine. 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. Pentaxim contains 12.5 micrograms of phenylalanine per 0.5 mL which can be dangerous for people with phenylketonuria, a rare genetic disease characterized by the accumulation of phenylalanine, which cannot be eliminated properly. Pentaxim contains 2 mg of alcohol (ethanol) per 0.5 mL dose and less than 1 mmol sodium (23 mg) per tablet.
Interactions: Due to the urinary elimination of the Hib polysaccharide capsular antigen, a positive result may be observed in a urine test 1 to 2 weeks after vaccination. Other tests should be done to confirm Hib infection during this time.
AE: Loss of appetite, nervousness, irritability, abnormal crying and screaming, drowsiness, 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 by 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). It has been shown that PTxd and FHA are two components of major importance for protection against pertussis. The PRP capsular polysaccharide (polyribosyl ribitol phosphate: PRP) is extracted from the culture of *Haemophilus influenzae* type b and conjugated to the tetanus protein (T) to give the PRP-T conjugate vaccine. Immunogenicity studies in infants have shown that, one month after the third dose of the primary vaccination, all (100%) developed a seroprotective antibody level (> 0.01 IU/mL) to both diphtheria and tetanus antigens. As for pertussis, one month after the third dose of the primary vaccination, 93% of infants achieved a four-fold rise in PT antibodies and more than 88% in FHA antibodies. At least 99% of children had seroprotective antibody titres to poliomyelitis virus types 1, 2 and 3 (≥ 5 as expressed by reciprocal of dilution in seroneutralisation). At least 97.2% of infants achieved anti PRP titres above 0.15 µg/mL one month after the third dose of the primary vaccination. After the first booster dose (16-18 months), all the toddlers developed protective antibodies against diphtheria (> 0.1 IU/mL), tetanus (> 0.1 IU/mL), poliomyelitis viruses (≥ 5 as expressed by reciprocal of dilution in seroneutralisation). The seroconversion rate in pertussis antibodies (titres higher than four-fold the pre-vaccinal titres) is at least 98% for PT (EIA) and 99% for FHA (EIA). An antibody titre anti-PRP ≥ 1.0 µg/mL was reached in all toddlers. A follow-up study of pertussis immunogenicity in children at 5-6 years of age has shown that the antibody titres anti-PT and anti-FHA of children vaccinated for primary course and booster with acellular combined vaccines were at least equivalent to those observed at the same age in children vaccinated with whole pertussis combined vaccines.

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