Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed) [Hexaxim®] Abridged Product Information

Diphtheria, Tetanus, Pertussis (acellular component), Hepatitis B (rDNA), poliomyelitis (inactivated), *Haemophilus influenzae* type B Conjugate Vaccine (adsorbed)

Hexaxim

6-IN-1 READY TO USE VACCINE

Product: Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed) [Hexaxim®]
Strength: 0.5 mL Suspension for Intramuscular Injection in pre-filled syringe
Presentation: 0.5 mL in 1 mL Type 1 pre-filled syringe with 2 separate needles (Box of 1's)
I: DTaP IPV HB Hib conjugate vaccine For the protection against infectious diseases such as diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by Haemophilus influenzae type b. Given to children from six weeks of age as a primary vaccination and as a booster dose. It is administered at the antero-lateral area of the upper thigh (preferred site) or the deltoid muscle in older children from 15 months of age.
C: Hypersensitivity to the active substances or to any of the excipients listed, to glutaraldehyde, formaldehyde, neomycin, streptomycin, or polymyxin B. Vaccination should not be given to individuals who suffered from a severe reaction affecting the brain within 7 days of a prior dose of pertussis vaccine, and to individuals with an uncontrolled condition or severe illness affecting the brain and nervous system or uncontrolled epilepsy. Intradermal or intravenous routes must not be used for vaccination.
W/P: Vaccination should be postponed when the individual has a moderate or high temperature or an acute illness. A dose of the vaccine should be carefully considered when the individual experiences any of the following within 48 hours after vaccination: fever of 40°C or above, collapse or shock like state with hypotonic hyporesponsive episode, or persistent, inconsolable crying lasting for 3 hours or more. The decision to give any further vaccine containing tetanus toxoid should be evaluated when the individual previously had Guillain Barré syndrome or brachial neuritis after the shot. It is recommended to wait until the end of the treatment or disease before giving the vaccine on individuals with weak immune system. For those who suffer from an acute or chronic illness including renal insufficiency, undiagnosed illness of the brain, or any problems with the blood that causes long time bruising and bleeding, consult your healthcare provider before receiving the vaccine. Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed) [Hexaxim®] contains phenylalanine, which may be harmful for individuals with phenylketonuria.
Interactions: The vaccine may be given at the same time with other vaccines such as pneumococcal vaccines, measles mumps rubella vaccines, rotavirus vaccines, or meningococcal vaccines. When given at the same time with other vaccines, it is important to give Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed) [Hexaxim®] at a different injection site.
AE: Loss of appetite, sleepiness, pain or swelling at the injection site, fever, crying, irritability, diarrhea, vomiting
PK/ PD: Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed) [Hexaxim®] is indicated for primary and booster vaccination of infants and toddlers from six weeks of age. The immune responses to Hib and pertussis antigens were evaluated after 2 doses in a subset of subjects receiving Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed) [Hexaxim] at 2, 4, 6 months of age. Studies on long term persistence of vaccine induced antibodies following varying infant / toddler primary series and following Hepatitis B vaccine given at birth or not have shown maintenance of levels above the recognized protective levels or antibody thresholds for the vaccine. Results of long term follow up demonstrated a dramatic reduction of the pertussis incidence following the second dose regardless of the vaccine used. The vaccine effectiveness against Hib invasive disease of DTaP and Hib combination vaccines has been demonstrated via an extensive (over five years follow up period) post marketing surveillance study. The vaccine effectiveness was of 96.7% for the full primary series, and 98.5% for booster dose. Non-clinical data reveal no special hazard for humans based on conventional repeat dose toxicity and local tolerance studies. At the injection sites, chronic histological inflammatory changes were observed, that are expected to have a slow recovery.

Date of Revision: February 2021
Reference: Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed) [Hexaxim®]. Philippines Prescribing Information.

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