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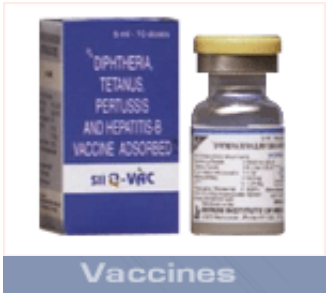

Vaccines

Quadrivalent Vaccine
SII Q-VAC®

DIPHTHERIA, TETANUS, PERTUSSIS AND HEPATITIS B VACCINE ADSORBED

DESCRIPTION

Diphtheria, Tetanus, Pertussis and Hepatitis B Vaccine Adsorbed (SII Q-VAC) as supplied by Serum Institute of India Ltd., is sterile, opaque, uniform suspension of diphtheria toxoid, tetanus toxoid, killed Bordetella pertussis bacilli and Hepatitis B surface antigen adsorbed on aluminum gel and suspended in isotonic sodium chloride solution. Surface antigen of the Hepatitis B virus (HBV) is obtained by culturing genetically engineered Hansenula polymorpha yeast cells having the surface antigen gene of the Hepatitis B virus. The Hepatitis-B surface antigen (HBsAg) expressed in the cells of Hansenula polymorpha is purified through several chemical steps using recombinant DNA procedures. Thiomersal is added as preservative.

Each dose of 0.5 ml contains :

Diphtheria Toxoid	$\geq$ 20 Lf to $\leq$ 30 Lf
Tetanus Toxoid	$\geq$ 5 Lf to $\leq$ 25 Lf
B. pertussis (whole cell)	$\geq$ 4 IU
HBsAg (rDNA)	$\geq$ 10 mcg
Al+++	$\leq$ 1.25 mg
Preservative: Thiomersal	$\leq$ 0.01%

DTP-HB vaccine does not prevent Hepatitis caused by other agents different from HBV (as virus A, C and E) but it is considered effective in preventing Hepatitis caused by the delta agent.

INDICATIONS

DTP-HB Vaccine Adsorbed is indicated for the active immunization of infants, at or above the age of 6 weeks of birth and of children through 6 years of age against Diphtheria, tetanus, whooping cough and Hepatitis B. In young children the EPI recommends as many antigens as possible to be administered at a single visit. The combined vaccine can be given safely and effectively at the same time as BCG, Measles and Polio vaccines (OPV and IPV), Hib, Yellow Fever vaccines and Vitamin A supplementation.

DOSAGE

For active immunization of infants and preschool children, it is recommended that three intramuscular injection of 0.5 ml be administered with an interval of four weeks between doses.

Although the customary age for first dose of primary immunization is two months but is now recommended to be given at 6 weeks of age. If for any reason it is delayed the same schedule may be used upto the sixth birth day.

Specifically, IAP recommends DTP to be given at 6, 10 and 14 weeks. A booster of DTP can be given at the age of 1 ½ years a reinforcing injection of the 0.5 ml

intramuscularly of the combination should be administered at 5 years of age (i.e. at the time of school entry).
SHAKE WELL BEFORE USE.

ADMINISTRATION
Do not inject subcutaneously or intravenously.
The vaccine vial should be well shaken to get an opaque suspension. **The vaccine should be administered by intramuscular injection.** The anterolateral aspect of the thigh is the preferred injection site for infants and deltoid for children. Another injection if coadministered with DTP-HB vaccine should be made at a different site. Only sterile needles and syringes should be used for each injection.

CONTRAINDICATIONS
Hypersensitivity to any component of the vaccine. It is a contraindication to use this or any other related vaccine after an immediate anaphylactic reaction associated with a previous dose.
It is a contraindication to administer the vaccine in the presence of any evolving neurological condition. Encephalopathy after a previous dose is a contraindication to further use. Immunization should be deferred during the cause of an acute illness. Vaccination of infants and children with severe, febrile illness should generally be deferred until recovery. However, the presence of minor illnesses such as mild upper respiratory infections with or without low-grade fever are not contraindications to further use. Elective immunization procedures should be deferred during an outbreak of poliomyelitis.

WARNINGS
Due to the long incubation period of Hepatitis B (upto 6 months or more), cases where prior exposure to Hepatitis B virus has taken place, vaccination may not be effective.
If any of the following events occur in temporal relation to receipt of DTP, the decision to give subsequent doses of vaccine containing the pertussis component should be carefully considered. There may be circumstances, such as a high incidence of pertussis, when the potential benefits outweigh possible risks, particularly since these events are not associated with permanent sequelae.

- Temperature 40.5°C (105°F) or more within 48 hours of a dose unexplained by another cause.
- Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours.
- Persistent, inconsolable crying lasting 3 hours or more occurring within 48 hours**.**
- Convulsions with or without fever occurring within three days.

Persons who experience Arthus-type hypersensitivity reactions or a temperature of 39.4°C (> 103° F) following a prior dose of tetanus toxoid usually have high serum tetanus antitoxin levels and should not be given even emergency doses of Td more frequently than every 10 years even if they have a wound that is neither clean not minor.
DTP should not be given to children with any coagulation disorder, including thrombocytopenia that would contraindicate intramuscular injection unless the potential benefit clearly outweighs the risk of administration.
Recent studies suggest that infants and children with a history of convulsions in first-degree family members (i.e. siblings and parents) have a 3:2 fold increased risk for neurologic events compared DTP vaccine and permanent neurologic damage. Infants and children with recognized possible or potential underlying neurologic conditions seem to be at enhanced risk for the appearance of manifestation of the underlying neurologic disorder within two or three days following vaccination.
The administration of DTP to children with proven or suspected underlying neurologic disorders that are not actively evolving must be decided on an individual basis.

PRECAUTIONS
Prior to an injection of any vaccine, all known precautions should be taken to prevent adverse reactions. This includes a review of the parent's history with respect to possible sensitivity and any previous adverse reactions to the vaccine or similar vaccines. Previous

immunization history, current health status and a current knowledge of the literature concerning the use of the vaccine under consideration. Immunosuppressed patients may not respond.
Prior to administration of DTP, health care personnel should inform the patient or guardian of the patient the benefits and risks of immunization, and also inquire about the recent health status of the patient to be injected. **Parents of a child with a family history of seizures should be informed that their child has an increased risk of seizures following DTP administration and should be instructed regarding appropriate medical care in the unlikely event of a seizure. Special care should be taken to ensure that the injection does not enter a blood vessel.** WHO does not recommend mixing different vaccines in one syringe before injection.
ADRENALINE INJECTION (1:1000) MUST BE IMMEDIATELY AVAILABLE SHOULD AN ACUTE ANAPHYLACTIC REACTION OCCUR DUE TO ANY COMPONENT OF THE VACCINE.
For treatment of severe anaphylaxis the initial dose of adrenaline is 0.1-0.5 mg (0.1-0.5ml of 1:1000 injection) given s/c or i/m. Single dose should not exceed 1 mg (1ml). For infants and children the recommended dose of adrenaline is 0.01mg/kg (0.01ml/kg of 1:1000 injection). Single paediatric dose should not exceed 0.5mg (0.5ml). The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be lifesaving.
As with the use of all vaccines the vaccine should remain under observation for not less than 30 minutes for possibility of occurrence of immediate or early allergic reactions. Efcorlin hydrochloride and antihistaminics should also be available in addition to supportive measures such as oxygen inhalation.

DRUG INTERACTIONS
As with other intramuscular injections, use with caution in patients on anticoagulant therapy. Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses) may reduce the immune response to vaccines. Short-term (< 2 weeks) corticosteroid therapy or intraarticular, bursal, or tendon injections with corticosteroids should not be immunosuppressive.

ADVERSE REACTIONS
Adverse reactions associated with the use of this vaccine include local redness, warmth, edema, and induration with or without tenderness, as well as urticaria and rash. Systemic reactions such as fever, headache, nausea and weakness may appear in a few subjects. Some data suggests that febrile reactions are more likely to occur in those who have experienced such responses after prior doses.
The frequency of local reactions and fever following DTP vaccination is significantly higher with increasing number of doses of DTP, while other mild to moderate systemic reactions. (e.g. fretfulness, vomiting) are significantly less frequent. If local redness 2.5 cm occurs the likelihood of recurrence after another DTP dose increases significantly. Evidence does not indicate a causal reaction between DTP vaccine and SIDS. Studies showing a temporal relation between these events are consistent with the expected occurrence of SIDS over the age range in which DTP immunization typically occurs. Deaths due to causes other than SIDS including deaths due to serious injections have occurred in infants following the administration of DTP. No association has been shown for hospitalizations due to infectious diseases and receipt of DTP.

Mild systemic reactions such as fever, drowsiness, fretfulness and anorexia occur quite frequently. Rarely, an anaphylactic reaction (i.e. hives, swelling of the mouth, difficulty in breathing, hypertension or shock and death) have been reported after receiving preparations containing diphtheria, tetanus and / or pertussis antigens.
Arthus-type hypersensitivity reactions characterized by severe local reactions (generally starting 2 to 8 hours after an injection), may follow receipt of tetanus toxoid.
Moderate to severe systemic events, including high fever (i.e. temperature of 40.5°C (105°F) and persistent, inconsolable crying lasting 3 hours or more. These events occur infrequently and appear to be without sequalae.
Occasionally, a nodule may be palpable at the injection site of adsorbed products for several weeks. Sterile abscesses at the site of injection have been reported (6 to 10 per million doses).

NERVOUS SYSTEM
The following neurologic illnesses have been reported as temporally associated with vaccine containing tetanus toxoid; neurological complications including cochlear lesion, brachial plexus neuropathies, paralysis of the radial nerve, paralysis of the recurrent nerve, accommodation paresis, and EEG disturbances with encephalopathy. It has been suggested that there is a causal relation between Guillain-Barre syndrome (GBS) and vaccines containing tetanus toxoid. In the differential diagnosis of polyradiculoneuropathies following administration of a vaccine containing tetanus toxoid should be considered as a possible etiology. Short-lived convulsions (usually febrile), or collapse (hypotonic hyporesponsive episode) occur infrequently and appear to be without sequelae.
More severe neurologic events, such as a prolonged convulsion, or encephalopathy, although rare, have been reported in temporal association with DTP administration. An analysis of these data failed to show any cause and effect association.

CARDIOVASCULAR SYSTEM
An infant who developed myocarditis several hours after immunization has been reported.

RESPIRATORY SYSTEM
Respiratory difficulties including apnea have been observed.

LOCAL
Rash and allergic reactions have been observed.

STORAGE
Diphtheria, Tetanus, Pertussis and Hepatitis B Vaccine Adsorbed (SII Q-VAC) should be stored at a temperature between 2°C and 8°C (35° to 46°F).

NOT TO BE FROZEN
Product, which has been exposed to freezing, should not be used.

PRESENTATION
0.5 ml - 1 dose ampoule carton.
5 ml-10 doses vial carton.