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Triple Antigen

Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) I.P

For Active Immunization against Diphtheria, Tetanus and Whooping Cough

DESCRIPTION

Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) (Sii Triple Antigen) as supplied by Serum Institute of India Ltd. is a sterile, whitish turibid, uniform suspension of diphtheria, tetanus toxoids and pertussis vaccine adsorbed on aluminium phosphate and suspended in isotonic sodium chloride solution.Each dose of 0.5 ml contains:

Diphtheria Toxoid	⩽25 Lf.
Tetanus Toxoid	⩾5 Lf.
B. Pertussis	⩾4 IU
Adsorbed on Aluminium Phosphate (AlPO4)	⩾1.5 mg.
Thiomersal	0.01% as preservative

This vaccine fulfils the I.P. requirements for Diphtheria Toxoid, Tetanus Toxoid and Pertussis Vaccine.

INDICATIONS

DPT Vaccine (Adsorbed) is indicated for the primary immunization of infants, at or above the age of 6 weeks, and of children through six years of age against diphtheria, tetanus and whooping cough.

DOSAGE

For the purpose of primary immunization it is recommended that 3 doses each of 0.5 ml should be inoculated on 3 separate occasions at 4 weeks interval.
The first dose should be given at approximately 6 weeks of age. Reinforcing injections of 0.5 ml should be given 12 months after the primary immunization and also between the ages of 4 to 6 years.

Although it is recommended that immunization be started at 6 weeks, if for any reason it is delayed, the same schedule may be used up to the sixth birthday.
A reinforcing injection of 0.5 ml. intramuscularly should be administered between four and six years of age (i.e. at the time of school entry). This booster dose is not necessary if the fourth primary immunizing dose has been administered after the fourth birthday.

ADMINISTRATION
DPT vaccine should be administered by deep intramuscular injection. The preferred site for injection is the anterolateral aspect of the upper thigh.
Only sterile needles and syringes should be used for each injection. The vaccine should be well shaken before use.
Each injection of the primary immunization series should be made into a different site with a sterile disposable syringe and needle.

ADVERSE REACTIONS
Mild local reactions consisting of erytherna, pain and tenderness, swelling and induration at the injection site are common, usually self-limited and subside without treatment. Persistent nodules at the site of injection have occurred following the use of an adsorbed vaccine, but this complication is unusual. Abscess at the site of injection has been reported (6-10 per million doses).
Mild to moderate systemic reactions occur frequently following injections of this vaccine. These usually consist of one or more of the following symptoms and signs: temperature elevation 38°C, drowsiness, fretfulness, anorexia, vomiting, irritability, persistent or unusual crying. These symptoms are most frequent during the first 24 hours following vaccine injection and may persist for one to two days.
The following adverse reactions -high fever (40.5°C), collapse, screaming episodes, convulsions, signs of encephalopathy which can be serious and, occasionally fatal have been reported following administration of preparations containing pertussis vaccine. The incidence of these reactions is unknown, but they seem to be exceedingly rare, if any of these reactions occur, further immunization against pertussis is contraindicated. See also **Contraindications and Precautions**.
Sudden-infant-death-syndrome (SIDS) has been reported following administration of vaccine containing diphtheria, tetanus toxoids and pertussis vaccine. The significance of these reports is not clear. It should be borne in mind that the three primary immunizing doses of these vaccine are usually administered to infants between the age of 6 weeks and 6 months and that approximately 85% of SIDS cases occur in the period from one through six months of age with the peak incidence at age two to four months.

CONTRAINDICATIONS
DPT Vaccine (Adsorbed) should not be administered to infants or children with high fever, or other evidence of acute illness or infection. The presence of an evolving or changing neurological disorder is a contraindication to receipt of this vaccine. While data to support

exclusion of pertussis immunization because of a family history of convulsive or other neurological disorders are scarce, a personal or family history of central nervous system disease or convulsions is considered a contraindication to use of this vaccine. Occurence of any of the following signs, symptoms or conditions following administration is a contraindication to further use of this product and or pertussis vaccine as the single antigen: fever over 40°C (104°F); convulsion(s) with or without accompanying fever; alterations of consciousness; focal neurologic signs; screaming episodes; shock; collapse; thrombocytopenia purpura.
DPT Vaccine (Adsorbed) should not be administered to children over six years of age or to adults because of the danger of reactions to diphtheria toxoid or to pertussis vaccine and because pertussis is less severe in these age groups than in infants and young children.
The specific contraindications adopted by individual national health authorities should reflect a balance between the risk from the vaccine and the risk from the disease. Because the risk from the vaccine remains extremely low in comparison to the risk from the disease in many developing countries, authorities there may choose to offer immunization to children who are mildly to moderately ill or malnourished.

PRECAUTIONS AND WARNING
Individuals receiving corticosteroids or other immunosuppressive drugs may not develop an optimum immunologic response. This product should be used only for infants and children from 6 weeks through six years of age. The possibility of allergic reactions in individuals sensitive to the components of the vaccine should be borne in mind. Adrenaline injection (1:1000) should be kept ready for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs. Frequent booster doses of tetanus toxoid in the presence of adequate or excessive serum levels of tetanus antitoxin have been associated with increased incidence and severity of reactions and should be avoided. If hypersensitivity to the diphtheria component is suspected, tetanus toxoid should be used for reinforcing doses.
A separate sterile syringe and needle should be used for each individual patient to prevent the transmission of hepatitis or other infectious agents.
DPT VACCINE (ADSORBED) SHOULD BE USED ONLY FOR INFANTS AND CHILDREN THROUGH SIX YEARS OF AGE.

WITHDRAWING THE VACCINE FROM A SEALED GLASS AMPOULE
Shake the ampoule to disperse the contents thoroughly immediately before withdrawing the dose. Tap the ampoule to ensure that the solution is in the lower portion rather than in the neck of the ampoule Wipe the neck of the ampoule with a suitable antiseptic using a sterile piece of cotton break off the top of the ampoule at the constriction by thumb pressure.

WITHDRAWING THE VACCINE FROM A RUBBER-STOPPERED VIAL
DO NOT REMOVE THE RUBBER STOPPER FROM THE VIAL

Shake the vial to disperse the contents thoroughly immediately before each withdrawal of vaccine. Apply a sterile piece of cotton moistened with a suitable antiseptic to the surface of the rubber stopper and allow to dry. Draw into the sterile syringe a volume of air equal to the amount of vaccine to be withdrawn from the vial. Pierce the centre of the rubber stopper with the sterile needle of the syringe. invert the vial, slowly inject into it the air contained in the syringe, and keeping the point of the needle immersed. withdraw into the syringe the required amount of vaccine. Then hold the syringe plunger steady and withdraw the needle from the vial.
Carefully insert the needle intramuscularly at the prepared injection site. In order to avoid intravenous injection, pull back the plunger of the syringe to make certain that no blood is withdrawn before injecting the desired dose.

STORAGE

Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) 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

Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) is supplied, ready for use, in rubber-stoppered multi-dose vials, and in single-dose glass ampoules.

i) 0.5 ml X 10 ampoules box
ii) 0.5 ml X 50 ampoules box
iii) 5 ml - 10 dose single vial carton
iv) 5 ml - 10 dose X 50 vials box