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## For Active Immunization against Diphtheria and Tetanus

Dual Antigen

Diphtheria and Tetanus Vaccine (Adsorbed) I.P.

Vaccines

**DESCRIPTION**

Diphtheria and Tetanus Vaccine (Adsorbed), (Sii Dual Antigen) as supplied by Serum Institute of India Ltd. is a sterile, whitish turbid, uniform suspension of diphtheria and tetanus toxoids adsorbed on aluminium phosphate and suspended in isotonic sodium chloride solution.

**POTENCY**

Each dose of 0.5 ml human dose contains:

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| Diphtheria Toxoid | ⩽25 Lf |
| Tetanus Toxoid | ⩾ 5 Lf |
| Adsorbed on Aluminium Phosphate ($AlPO_4$) | ⩾ 1.5 mg |
| Thiomersal | 0.01 % as preservative |

This vaccine fulfills the I.P. requirements for Diphtheria Toxoid and Tetanus Toxoid.

**INDICATIONS**

Diphtheria and Tetanus Vaccine (Adsorbed) is indicated for the primary immunization of infants, at or above the age of two months, and of pre-school children against diphtheria and tetanus in whom simultaneous immunization against pertussis is not indicated.

**DOSAGE**

Three injections of 0.5 ml at least four weeks apart followed by a fourth dose 6 to 12 months later.

For primary immunization of infants and preschool children it is recommended that three intramuscular injections of 0.5 ml be administered with an interval of four to eight weeks between doses. A fourth injection of 0.5 ml. should be administered intramuscularly approximately one year after initial injection.

Although it is recommended that immunization be started at two to six months of age, if for any reason it is delayed, the same schedule may be used throughout the preschool period.

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)

**ADMINISTRATION**

The vaccine should be administered by intramuscular injection. The preferred site for injection in infants and young children is the anterolateral aspect of the upper thigh or the deltoid muscle in older children.

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.

**ADVERSE REACTIONS**

Mild local reactions consisting of pain, erythema, tenderness, and induration at the injection site are common and may be associated with systemic reactions including mild to moderate transient fever, and irritability. Persistent nodules at the site of injection have occurred following the use of an adsorbed vaccine, but this complication is unusual

**CONTRAINDICATIONS**

Diphtheria and Tetanus Vaccine (Adsorbed) should not be administered to infants or

children with high fever, or other evidence of acute illness.

Elective immunization of individuals over six months of age should be deferred during an outbreak of poliomyelitis,

Diphtheria and Tetanus Vaccine (Adsorbed) should not be administered to older children (after six years of age) or to adults because of the danger of reactions to diphtheria toxoid.

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.
The possibility of allergic reactions in individuals sensitive to the components of the product should he 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.

**WITHDRAWING THE VACCINE FROM 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 and Tetanus Vaccine (Adsorbed) should be stored between 2°C and 8°C (35°F and 46°F). **NOT TO BE FROZEN**
Product which has been exposed to freezing should not be used.

**PRESENTATION**

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

- 0.5 ml X 10 ampoules box
- 5 ml - 10 dose X 50 vials box

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