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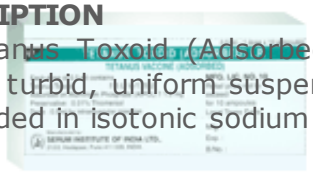
FAQ

For Active Immunization against Tetanus.

Tetanus Toxoid (Adsorbed) I.P.



Tetanus Vaccine (Adsorbed)

Vaccines

DESCRIPTION

Sii Tetanus Toxoid (Adsorbed) as supplied by Serum institute of India Ltd. is a sterile, whitish turbid, uniform suspension of tetanus toxoid adsorbed on aluminium phosphate and suspended in isotonic sodium chloride solution.

POTENCY

Each dose of 0.5 ml human dose contains:

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

This vaccine fulfils the I.P. requirements for Tetanus Toxoid (Adsorbed)

INDICATIONS

As Tetanus can occur in cases of even minor injuries it is advisable to actively immunize every person in general. With this aim in view, it is desirable: To actively immunize all children from the age of 6 weeks onwards.

- To protect infants against the risks of tetanus neonatorum by immunizing pregnant mothers.
- To actively immunize civil population particularly those who are exposed to occupational risks such as road workers, athletes agricultural workers, industrial workers etc.
- To actively immunize civil and defense personnel, home guards and police personnel.

DOSAGE

The full basic course of immunisation against tetanus toxiod consists of three primary doses of 0.5ml at least four weeks apart, followed by booster doses at 18 months, 5 years, 10 years and 16 years and then every 10 years.

PROTECTION OF THE NEW BORN AGAINST TETANUS

For prevention of neonatal tetanus, tetanus toxoid is recommended for immunization of women of childbearing age, and especially pregnant women. Tetanus toxoid may be safely administered during pregnancy and should be given to the mother at first contact or as early as possible in pregnancy. Pregnancy: After completing the full basic course of 7 doses, there is no need for additional doses during pregnancy at least for the next 10 years; thereafter a single booster would be sufficient to extend immunity for another 10 years. For pregnant woman who have not had previous immunisation, at least 2 doses of tetanus toxoid at four weeks interval, 2 dose at least 2 weeks before delivery should be given during pregnancy so that protective antibody would be transferred to the infant in order to prevent neonatal tetanus.

VACCINATION OF INJURED PERSONS

For those subjects who have proof of either completing their course of primary immunizations containing tetanus toxoid or receiving a booster shot within the previous 5

years no additional dose of tetanus toxoid is recommended.
If more than 5 years have elapsed, and infection with tetanus because of injury or other cause is suspected, 0.5ml of the adsorbed tetanus toxoid should be given immediately. Where the immunization history is inadequate 1500 IU tetanus antiserum and 0.5ml Tetanus toxoid should be injected, with separate syringes, to different body sites. (If available, 250 units of tetanus immune globulin (human origin) can be substituted for the tetanus antiserum).
A second 0.5ml dose of toxoid is recommended after 2 weeks and a third dose after a further 1 month.
(A note of caution : if Tetanus antiserum from heterologous origin is used in prophylaxis, the patient should be tested for sensitivity to horse serum protein prior to its administration. It is desirable to have 1 ml of Epinephrine Hydrochloride solution (1 : 1000) immediately available and the normal precautions followed when injecting antitoxins).

ADMINISTRATION
The vaccine should be administered by deep intramuscular injection. Tetanus toxoid should be injected intramuscularly into the deltoid muscle in women and older children. If there are indications for the use of tetanus toxoid in younger children the preferred site for intramuscular injection is the anterolateral aspect of the upper thigh since it provides the largest muscular area.
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
Sii Tetanus Toxoid (Adsorbed) should not be administered to infants or children with high fever, or other evidence of acute illness.
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 WARNINGS
Individuals receiving corticosteroids or other immunosuppressive drugs may not develop an optimum immunologic response. The possibility of allergic reactions in individuals sensitive to the component of the product should be borne in mind. A separate sterile syringe should be used for each individual patient to prevent the transmission of hepatitis or other infectious agents.

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
Sii Tetanus Toxoid (Adsorbed) should be stored between 2°C and 8°C (35° and 46°F).
NOT TO BE FROZEN.
Product which has been exposed to freezing should not be used.

PRESENTATION
Sii Tetanus Toxoid (Adsorbed) is supplied, ready to use, in rubber-stoppered multi-dose vials, and in single-dose glass ampoules in the following packing:
i) 0.5 ml. X 10 ampoules box.
ii) 0.5 ml. X 50 ampoules box.
iii) 5 ml. - 10 dose X 50 vials box.