SERUM INSTITUTE OF INDIA PVT. LTD.

ADSORBED TETANUS VACCINE B.P.
TETANUS TOXOID
Tet/Vac/Ads

DESCRIPTION
Adsorbed Tetanus Vaccine B.P. (Tetanus Toxoid) is prepared by detoxification of the sterile filtrate of broth cultures of Clostridium tetani with formalin and heat. The toxoid is purified by chemical methods and is adsorbed onto aluminium phosphate as adjuvant. Thiomersal is added as preservative. The vaccine has the appearance of a greyish-white suspension and does not contain any horse serum protein. Therefore it does not induce sensitization to sera of equine origin. The vaccine meets the requirements of W.H.O., B.P. and I.P. when tested by the methods outlined in W.H.O., TRS. 980 (2014), B.P. and I.P.

POTENCY
Each single 0.5 ml human dose contains:
Tetanus Toxoid ⩾ 5 Lf (⩾ 40 IU)
Adsorbed on Aluminium Phosphate, Al^{+++} ⩽ 1.25 mg
Preservative : 0.005% Thiomersal

INDICATIONS
The vaccine is used for the prevention of tetanus in infants, children and adults, especially those liable to be exposed to tetanus infection and persons engaged in outdoor activities e.g. gardeners, farm workers and athletes.
Tetanus toxoid vaccine is also used in the prevention of neonatal tetanus by immunizing women of childbearing age, and also in the prevention of tetanus following injury. The vaccine can be safely and effectively given simultaneously with BCG, Measles, Polio vaccines (IPV and OPV), Hepatitis B , Yellow fever vaccine, *Haemophilus influenzae* type b, Varicella vaccine and Vitamin A supplementation.

APPLICATION AND DOSAGE
The full basic course of immunization against tetanus toxoid consists of two primary doses of 0.5 ml at least four weeks apart, followed by the third dose 6-12 months later. To maintain a high level of immunity further 0.5 ml booster doses are recommended at every feasible interval (for adults usually 5 to 10 years).

PROTECTION OF THE NEWBORN 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. A five dose schedule is recommended for previously unimmunized women of childbearing age : after the basic course of immunization with three doses, two additional booster doses should be given, at least one year after the previous dose or during the subsequent pregnancy.

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 addtional 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, 0.5 ml of the adsorbed tetanus toxoid should be given immediately. Where the immunization history is inadequate 1500 IU (3000 old AU) tetanus antiserum and 0.5 ml 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 0.5 ml dose of toxoid is recommended after 2 weeks and a third dose after a further 1 month. (A note of caution : if horse-origin tetanus antiserum 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 Adrenaline solution (1 : 1000) immediately available and the normal precautions followed when injecting antitoxins).

METHOD OF INOCULATION
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 mass. Only sterile needles and syringes should be used for each injection. The vaccine should be well shaken before use.

Once opened, multi-dose vials should be kept between +2°C and +8°C. Multi-dose vials of TT from which one or more doses of vaccine have been removed during an immunisation session may be used in subsequent immunisation sessions for upto a maximum of 28 days, provided that all of the following conditions are met (as described in the W.H.O. policy statement: Handling of multi dose vaccine vials after opening, W.H.O./IVB/14.07):

- The vaccine is currently prequalified by W.H.O.;
- The vaccine is approved for use for up to 28 days after opening the vial, as determined by W.H.O.;
- The expiry date of the vaccine has not passed;
- The vaccine vial has been, and will continue to be, stored at W.H.O.- or manufacturer recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

The vaccine should be visually inspected for any foreign particulate matter and / or variation of physical aspect prior to administration. In event of either being observed, discard the vaccine.

REACTIONS:
Reactions are generally mild and confined to the site of injection. Some inflammation may occur together with transient fever, malaise and irritability. Occasionally a nodule may develop at the site of injection but this is rare. An increased severity of reactions to vaccination may be observed in subjects who have had many booster immunizations.

CONTRAINDICATIONS AND WARNINGS
The vaccine should not be given to persons who showed a severe reaction to a previous dose of tetanus toxoid Immunisation should be deferred during the course of any febrile illness or acute infection. A minor febrile illness such as a mild upper respiratory infection should not preclude immunisation.

PRECAUTIONS
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 (0.1-0.5 ml of 1:1000 injection) given s/c or i/m. Single dose should not exceed 1 mg (1 ml). For infants and children the recommended dose of adrenaline is 0.01 mg/ kg (0.01 ml/ kg of 1:1000 injection). Single paediatric dose should not exceed 0.5 mg (0.5 ml). The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be lifesaving. It should be used at the first suspicion of anaphylaxis.

As with the use of all vaccines the vaccinees should remain under observation for not less than 30 minutes for possibility of occurrence of immediate or early allergic reactions. Hydrocortisone and antihistaminics should also be available in addition to supportive measures such as oxygen inhalation.
There is an increased incidence of local and systemic reactions to booster doses of tetanus toxoid when given to previously immunized persons.
Special care should be taken to ensure that the injection does not enter a blood vessel.

IT IS EXTREMELY IMPORTANT WHEN THE PARENT, GUARDIAN, OR ADULT PATIENT RETURNS FOR THE NEXT DOSE IN THE SERIES, THE PARENT, GUARDIAN, OR ADULT PATIENT SHOULD BE QUESTIONED CONCERNING OCCURRENCE OF ANY SYMPTOMS AND/OR SIGNS OF AN ADVERSE REACTION AFTER THE PREVIOUS DOSE.

DRUG INTERACTIONS
If passive immunisation for tetanus is needed, TIG (Human) is the product of choice. It provides longer protection than antitoxin of animal origin and causes few adverse reactions.
As with other Intramuscular injections, use with caution in-patients on anticoagulant therapy.
Immunosuppressive therapies may reduce the immune response to vaccines.

IMMUNE DEFICIENCY
TT vaccine may be used in children with known or suspected HIV infection. Although the data are limited and further studies are being encouraged, there is no evidence to date of any increased rate of adverse reactions using this vaccine in symptomatic or asymptomatic HIV infected children.

STORAGE OF THE VACCINE.
The vaccine should be stored in a dry, dark place at a temperature between 2 to 8°C. Transportation should also be at 2 to 8°C. DO NOT FREEZE.

SHELF LIFE
Thirty six months from the date of manufacture.

PRESENTATION
1 dose ampoule of 0.5 ml
10 dose vial of 5 ml
20 dose vial of 10 ml

THE VACCINE VIAL MONITOR (Optional)

✓ Inner square lighter than outer circle.
If the expiry date has not passed, USE the vaccine.
✓ At a later time, inner square still lighter than outer circle.
If the expiry date has not passed, USE the vaccine.
✗ Discard point:
Inner square matches colour of outer circle.
DO NOT use the vaccine.
✗ Beyond the discard point:
Inner square darker than outer ring.
DO NOT use the vaccine.

Vaccine Vial Monitors (VVMs) are part of the label on Adsorbed Tetanus Vaccine B.P. supplied through Serum Institute of India Pvt. Ltd. The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.
The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, then the vial should be discarded.

Manufactured by:
SERUM INSTITUTE OF INDIA PVT. LTD.
212/2, Hadapsar, Pune 411028, INDIA

Protection from birth onwards

20012800/1

Reason for issue: Addition of "PVT." in Co. Name			Specification: Printed on bible paper 40 gsm.	
Customer: Exports				
Product: ADSORBED TETANUS VACCINE B.P. TETANUS TOXOID Reduced Thiomersal			Colour: Pantone 327C and Pantone 072 C	
Item Code number: 20012800/1		Specification No.:		Artwork made to: 100%
Supercedes Item Code: 20012800/0			Dimensions: 75 x 198 mm	
PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	MEDICAL DEPARTMENT	QUALITY ASSURANCE

File Name: E:\Packaging artworks as on 090212\Artworks SII Pvt Ltd 231015\Insert\Exports\TT insert BP - RT (English Language).cdr Rev. on: 22.02.16
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