SUMMARY PRODUCT CHARECTERISTICS

Tetanus Toxoid Vaccine Adsorbed (TT)

DESCRIPTION	Tetanus Toxoid Vaccine Adsorbed is prepared by detoxification of the sterile filtrate of broth cultures of Clostridium Tetani with formalin and heat. The Toxoid is purified by chemical method 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 if does not induce sensitization to sera of equine origin. The vaccine meets the requirements of WHO, EP, and IP when tested by the methods of outlined in WHO TRS 9080 (2014), EP and IP.
POTENCY	Each single 0.5ml of human dose contains: Tetanus Toxoid ≥ 5Lf (≥40 IU) Adsorbed on Aluminum Phosphate, Al^{+++}≤ 1.25mg. Preservative: 0.005% Thiomersal
THERAPEUTIC INDICATIONS	The vaccines is used for prevention of tetanus in infants, children and adults, especially those liable to be exposed to tetanus infection and persons engaged in outdoor activities eg. Gardeners, farm workers and athletes. Tetanus Toxoid vaccine is also used in the prevention of neonatal tetanus by immunizing women of child bearing age, and also in prevention of tetanus following injury. The vaccines can be safely and effectively given simultaneously with BCG, Measles, Polio Vaccines (IPV and OPV), Hepatitis B, Yellow fever vaccines, H. Influenzae type B, Varicella vaccine and Vitamin A supplementation.
DOSAGE & METHOD OF ADMINISTRATION	The full basic course of immunization against tetanus consist of two primary doses of 0.5ml at least 4 weeks apart, followed by the 3rd dose 6-12 later. To maintain a high level immunity further 0.5ml booster doses are recommended at every feasible interval (for adults usually 5-10 years)
CONTRAINDICATONS	Person who showed severe reaction to a previous dose of tetanus toxoid.
SPECIAL WARNINGS & PRECAUTION FOR USE	The immunization should be deferred during the course of any febrile illness or acute infection and also minor febrile illness such as mild upper respiratory infection. 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. 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. Efcorlin hydrochloride 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
INTERACTION WITH OTHER MEDICAL PRODUCTS & OTHER FORM OF INTERACTION	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.
UNDESIRABLE EFFECTS	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
STORAGE OF VACCINES	The vaccine should be stored in a dry, dark place at a temperature between 2-8°C. Transportation should also be at 2-8°C. DO NOT FREEZE.
PRESENTATION	1 dose ampoule of 0.5ml. 10 dose vial of 5 ml. 20 dose vial of 10 ml
MARKETING AUTHORIZATON HOLDER	Serum Institute of India, Ltd.
PRODUCT REGISTRATION NUMBER	BHU-DRA/B02693 BHU-DRA/B02694 BHU-DRA/B02695