

For the use of Registered Medical Practitioner or Hospital or Laboratory only.

TETANUS VACCINE (ADSORBED) I.P.

ShanTT®

Prescribing Information

Qualitative and Quantitative Composition : *ShanTT*® is a sterile suspension of Tetanus Toxoid adsorbed on Aluminium Phosphate in an isotonic Sodium Chloride solution. The vaccine on shaking is a whitish turbid liquid.

Each dose of 0.5 mL contains

Tetanus Toxoid	≥ 40 IU
Aluminium Phosphate Gel equivalent to Al ⁺⁺⁺	0.425 mg
Thiomersal I.P.	0.025 mg*
* Thiomersal content for multi dose vial	0.05 mg

Clinical Pharmacology

Tetanus is manifested primarily by neuromuscular dysfunction caused by a potent exotoxin of *Clostridium tetani*.

Tetanus is an important endemic disease in India. Prior to national immunization programme, an estimated 3.5 lakh children died annually due to neonatal tetanus. Neonatal Tetanus occurs among infants born under unhygienic conditions to inadequately vaccinated mothers. Vaccinated mothers confer protection to their infants through transplacental transfer of maternal antibody. The efficacy of Tetanus Toxoid was determined on the basis of immunogenicity studies with a comparison to a serological correlate of protection (0.01 antitoxin units/mL) established by the Panel on review of Bacterial Vaccines & Toxoids.

Therapeutic Indications

ShanTT® is indicated for

- Active immunization of children aged 7 years or older, and adults.
- Active immunization of pregnant women.
- Active immunization in those who are exposed to occupational hazards such as road workers, athletes, agricultural workers, industrial workers or after sustaining any injuries.

Posology

The recommended dose of the vaccine is 0.5 mL to be administered intramuscularly.

Method of Administration

ShanTT® 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 shaken well before use. Each injection of the primary immunization series should be made into a different site.

Contra-indications

ShanTT® should not be administered to subjects with either known hypersensitivity to any component of the vaccine, or having shown signs of hypersensitivity after previous administration of Tetanus vaccine. As with other vaccines, the administration of *ShanTT*® should be postponed in subjects suffering from acute severe febrile illness or other evidence of acute illness. Elective immunization procedures should be deferred during the outbreak of poliomyelitis.

Special precautions :

Vaccination should be preceded by a review of the medical history (especially with regard to previous vaccination and the possible occurrence of undesirable events) and a clinical examination. Individuals receiving corticosteroids or other immunosuppressive drugs may not develop an optimum immunologic response.

***ShanTT*® should under no circumstances be administered intravenously.**

Clinical Experience¹

In a prospective multicentric phase III study, 204 subjects were screened of which 174 subjects received *ShanTT*® vaccine, post vaccination immune response was observed in 98.0% subjects. The post vaccination GMT was 1.8 IU/mL. A 3.6 fold rise in titre was observed post vaccination.

Local side effects

The most frequently reported local reaction was pain at the injection site, which was observed in 29.3% and followed by swelling in 4.0% at the site of vaccine administration.

Systemic side effects

Among the systemic side effects, fever and headache was reported in only 2.3% & 1.7% subjects respectively.

Interactions with other medicaments and other forms of interaction :

As with other intramuscular injections, use with caution on patients on anticoagulant therapy. Immunosuppressive therapies may reduce the immune response to vaccines.

Pregnancy Category C

Adverse Reactions

Adverse reactions may be local and include redness, warmth, edema, and induration with or without tenderness as well as urticaria and rash.

Shelf life

36 months from the date of manufacture.

Special precautions for storage

ShanTT® should be stored at +2°C to +8°C.

Do not freeze. Discard if the vaccine has been frozen.

Presentation

ShanTT® [Tetanus Vaccine (Adsorbed)] is supplied as ready to use, monodose, 10 dose vials and 20 dose vials.

Instruction for use/handling:

How to use *ShanTT*®

ShanTT® is presented as suspension. Upon storage, a white deposit and clear supernatant may be observed. The vaccine vial should be **shaken adequately** in order to obtain a homogeneous turbid white suspension. The vial should be visually inspected for any foreign particulate matter. Physical aspects like cap and the seal should be inspected for integrity of container closure system. In the event of either of the above being observed, discard the vaccine.

When using a multi dose vial, each dose should be taken with a sterile needle and syringe. Each dose of vaccine should be withdrawn under strict aseptic conditions and precautions to avoid contamination of the contents.

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