1. NAME OF THE MEDICINAL PRODUCT (GENERIC NAME)

Tetanus Vaccine (Adsorbed) I.P.

Suspension for injection by intramuscular route.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 ml contains:
Tetanus toxoid greater than or equal to 5 Lf to less than or equal to 25 Lf
Aluminium Phosphate (Mineral Carrier) - 1.5 mg
Thiomersal I.P. (preservative) - 0.01%w/v

3. PHARMACEUTICAL FORM (DOSAGE FORM AND STRENGTH)

Dosage form:
Tetanus Vaccine (Adsorbed) I.P. 0.5 ml single dose in Ampoules
Tetanus Vaccine (Adsorbed) I.P. 5.0 ml multi dose (10 doses) in Vials

Strength:
Each 0.5 ml contains Tetanus toxoid greater than or equal to 5 Lf to less than or equal to 25 Lf.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- For active immunization against tetanus.

4.2 Posology and method of administration

Inject intramuscularly deep into the deltoid muscle in adults and older children or anterolateral aspect of upper thigh (mid-thigh laterally) in younger children.

The vaccine should not be injected into the gluteal areas where there may be a major nerve trunk.

A sterile needle and a sterile syringe should be used for each injection. Before injecting, the skin over the site to be injected should be cleansed with a suitable germicide. The vaccine should be visually inspected for any foreign particulate matter and any variation in physical aspect prior to administration and in the event of either being observed discard the vaccine.

Posology:
Tetanus vaccine consists of two primary doses of 0.5ml to be administered at least four weeks apart followed by the third dose, at least six months later.

To maintain immunity of women against tetanus through the child - bearing period a total of five doses are recommended. A fourth dose should be given at least one year after the third dose, and a fifth dose at least one year after the fourth dose.

The safety of this medicinal product for use in human pregnancy has not been established in controlled clinical trials. Clinical experience with Tetanus toxoid suggests that no harmful effects on the course of pregnancy or on the fetus and the neonate are to be expected.

In previously non immunized women, two doses of Tetanus vaccine are recommended during pregnancy, at least 4 weeks apart. The second dose should be administered at least two weeks before childbirth, to prevent maternal and neonatal tetanus.

Tetanus toxoid should also be given in situations where a risk of developing tetanus from other sources (e.g.: injuries) exists. At least two doses with one-month interval will be required to provide basic protection in a previously unimmunized person and additional booster dose will be required to maintain protection over time.
Refer national immunization schedules for more details.

Method of administration:
When administration of tetanus vaccine is indicated (e.g.: tetanus prone wound) the vaccine should be administered at a separate site, with separate needle and syringe.

Persons who have not completed primary immunization against tetanus or whose vaccine history is unknown or uncertain should be immunized with tetanus vaccine. Full cycle of vaccinations plan is 0,1,6-12month (two initial doses in time intervals not shorter than 4-6 weeks, the third supplementary dose after 6 months to 1 year from the second vaccination) booster vaccination, one dose every 10 years from the last vaccination.

Tetanus vaccine may be given at the same time as BCG, measles, rubella, mumps, polio (OPV and IPV), Hepatitis B, Haemophilus influenza type b and yellow fever vaccines and vitamin A supplementation.

4.3 Contraindications

It is a contraindication to use this vaccine after anaphylaxis or other serious allergic reaction following a previous dose of this vaccine, any other tetanus vaccine - containing vaccine, or any component of this vaccine. The vaccine should not be administered to anyone with high fever or other evidence of acute illness.

4.4 Special warnings and precautions for use

Care is to be taken by the health care provider for the safe and effective use of Tetanus vaccine. Special care should be taken to ensure that the injection does not enter a blood vessel.

Shake well before withdrawing each dose to homogenize the suspension, avoid foaming. Discard if vaccines cannot be resuspended to a homogenous suspension.

Individuals receiving corticosteroids or other immune suppressive drugs may not develop an optimum immunological response.

Intramuscular injections should be given with great care in patients suffering from thrombocytopenia or other coagulation disorders.

As with the use of all vaccines, the person who has taken the vaccine should be under observation for not less than 30 minutes for possibility of occurrence of immediate or early allergic reactions. Hydrocortisone and antihistamines should also be available in addition to supportive measures such as oxygen inhalation.

Epinephrine (1:1000) injection and other appropriate agents and equipment must be immediately available when an acute anaphylactic reaction occur due to any component of the vaccine.

Persons infected with human immunodeficiency virus (HIV) whether asymptomatic or symptomatic, should be immunized with tetanus vaccines according to standard schedules.

A separate sterile syringe should be used for each individual patient to prevent the transmission of hepatitis or other infectious agents.

4.5 Interaction with other medicinal products and other forms of interaction (Drug Interactions)

Immunosuppressive therapies may reduce the immune response to tetanus vaccine. As with other Intramuscular injections, use with caution in patients on anticoagulant therapy.

4.6 Use in special populations (such as pregnant women, lactating women, pediatric patients, geriatric patients etc.) (Pregnancy and Lactation)

There is no evidence that tetanus vaccine is teratogenic. Tetanus toxoid should be given to inadequately immunize pregnant women because it affords protection against neonatal tetanus. In fact, it is recommended to give the vaccine to pregnant women with greater coverage. Waiting until the second trimester is a reasonable precaution to minimize the theoretical teratogenic concern.

Tetanus vaccine does not affect the safety of mothers who are Breast feeding to their infants. Breast feeding does not adversely affect the immune response and is not a contraindication for vaccination.

4.7 Effects on ability to drive and use machines

Tetanus vaccine is not reported to have any influence on the ability to drive and use machines.

4.8 Undesirable effects

Some temporary tenderness, redness, and pain in duration may develop at the site of injection 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 adsorbed vaccines, but this complication is unusual. General reactions are uncommon but may include headache, lethargy,

malaise, myalgia. Acute anaphylactic reactions, urticaria, angioneurotic oedema, serum sickness and peripheral neuropathy occasionally occur.

There is increased incidence of local and systemic reactions to booster doses of tetanus vaccine when given to previously immunized persons.

4.9 Overdose

The data on overdose of DANO-TT® is not available.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of action

Tetanus is a condition manifested primarily by neuromuscular dysfunction caused by a potent exotoxin released by C. tetani. Protection against disease is due to the development of neutralizing antibodies to the tetanus toxin. A serum tetanus antitoxin level of at least 0.01 IU/mL, measured by neutralization assays, is considered the minimum protective level A level ≥0.1 IU/mL by ELISA has been considered as protective.

5.2 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccines
ATC code JH07AM01.
No data pertaining pharmacodynamic properties is available.

5.3 Pharmacokinetic properties

No data pertaining pharmacokinetic studies is available.

6. PRECLINICAL SAFETY DATA (NON-CLINICAL PROPERTIES)

6.1 Animal Toxicology or Pharmacology

Single dose (5 Lf) toxicity study of intramuscular tetanus vaccine conducted in five male and five female Swiss albino mice for a duration of 14 days in the year 2013 revealed no significant treatment related effects on food intake, body weight gain and clinical signs in the mice. No mortalities were recorded in this study period.

Single dose (5 Lf) toxicity study of intramuscular tetanus vaccine conducted in five male and five female wistar rats for a duration of 14 days in the year 2013 revealed that the food intake, the body weight gain was normal in rats, there was no gross changes in the vital organs observed after euthanization and that there were physical, physiological and behavioural changes in the studied rats. No mortalities were recorded after administration of single dose tetanus vaccine in this study period.

7. DESCRIPTION

The Vaccine is a turbid suspension having greyish- white colour.

DANO-TT® is a sterile vaccine for intramuscular administration. It contains tetanus toxoid antigen. Tetanus toxin is produced by growing Clostridium tetani (Harvard Strain No. 49205) in modified Mueller & Miller Medium. This strain is highly toxicogenic and non-sporing variant of the classical Clostridium tetani.

Tetanus toxin is detoxified with formaldehyde, concentrated by ultrafiltration, and purified by precipitation followed by dialysis, and sterile filtration.

Each Dose of DANO-TT® contains 1.5 mg of Aluminium phosphate (Mineral carrier) and 0.01%w/v Thiomersal I.P. (Preservative).

DANO-TT® is available in vials and ampoules.

8. PHARMACEUTICAL PARTICULARS

8.1 List of Excipients

Each dose of 0.5 ml contains:	
Tetanus Toxoid	≥5Lf to ≤25Lf
Aluminium Phosphate (Mineral Carrier)	1.5 mg
Thiomersal I.P. (Preservative)	0.01% w/v

8.2 Incompatibilities

None Known.

8.3 Shelf life

Thirty-six months from the date of manufacture.

9. NATURE AND CONTENTS OF CONTAINER (PACKAGING INFORMATION)

The vaccine is available in -
0.5ml (one dose) in Ampoule, Pack size 50x0.5ml Ampoules
5 ml (Ten doses) in Vial, Pack size 50x5ml Vials

9.1 Storage and Handling Instructions

9.1.1 Special precautions for storage

DANO-TT® should be stored and transported between 2°C to 8°C. “IT MUST NOT BE FROZEN”.

Once opened Multi - dose vials should be kept between 2°C to 8°C and Multi-dose vials of DANO-TT® from which one or more doses of vaccine has been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 4 weeks, provided that all of the following conditions are met (as described in the WHO policy statement: The use of opened multi dose vials in subsequent immunization sessions. WHO/V&B/00.09).

The expiry date has not passed.

The vaccine is stored under appropriate cold - chain conditions.

The vaccine vial septum has not been - submerged in water.

Aseptic technique has been used to withdraw all doses.

If not sure of the above conditions, it is recommended to discard the multi dose presentation at the end of day's shift.

Any unused product or waste material should be disposed of in accordance with local requirements.

9.1.1 Special precautions for disposal

General vaccine disposal guidelines for:

- Expired or compromised vaccine-sometimes unused vaccine and diluent doses, unopened vials, expired vials, and potentially compromised vaccine may be returned for credit, even if they must be discarded. Contact your immunization program* and/or the vaccine manufacturer for vaccine-specific information.
- Open and broken vials and syringes, manufacturer-filled syringes that have been activated, and vaccine pre-drawn by providers-these cannot be returned and should be discarded according to your state requirements.
- Empty vaccine vials-most are not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container. However, check and comply with your local requirements for disposal.
  Medical waste disposal requirements may vary from state to state because they are set by state environmental agencies. Contact your immunization program or state environmental agency for guidance to ensure your facility's vaccine disposal procedures comply with applicable local regulations.

10. PATIENT COUNCELLING INFORMATION

General
Epinepherine injection (1:1000) and other appropriate agents and equipment must be immediately available when an acute anaphylactic reaction occur.

Prior to the administration of DANO-TT®, the vaccine recipient's current health status and health history should be reviewed. This includes a review of the immunization history of the patient, the presence of any contraindications to immunization, and any adverse events after previous

immunizations to allow an assessment of the benefits and risks of vaccination. (See CONTRAINDICATIONS and WARNINGS).

If DANO-TT® is administered to immunocompromised persons (whether from disease or treatment) the expected immune response may not be obtained.

Information for Patients
Prior to administration of DANO-TT®, patients, parents or guardians should be informed by the health care provider of the benefits and risks of immunization and of the importance of completing the primary immunization series or receiving recommended booster doses.

The health care provider should inform the patient, parent, or guardian of the potential for adverse reactions that have been temporally associated with DANO-TT® or other vaccines containing similar ingredients. Patients, parents or guardians should be instructed to report any suspected adverse reactions to their health care provider.

Drug Interactions
Patients who are on immunosuppressive therapy, including alkylating agents, antimetabolites, cytotoxic drugs, irradiation, or corticosteroids (used in greater than physiologic doses), may have a reduced immune response to vaccines.

No safety and immunogenicity data are available on the concomitant administration of DANO-TT® vaccine with other licensed vaccines.

Carcinogenesis, Mutagenesis, Impairment of fertility
No studies have been performed with DANO-TT® to evaluate carcinogenicity, mutagenic potential, or impairment of fertility.

Pregnancy Category C
Animal reproduction studies have not been conducted with DANO-TT®. It is also not known whether DANO-TT® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DANO-TT® should be given to a pregnant woman only if clearly needed.

Nursing Mothers
It is not known whether DANO-TT® is excreted in human milk. As we are aware of many drugs are excreted in human milk, caution should be exercised when DANO-TT® is administered to a nursing woman.

Paediatric Use
DANO-TT® is not approved for use in infants and children younger than 7 years of age. The safety and effectiveness of DANO-TT® in this age group have not been established.

Geriatric Use
No studies have been performed with DANO-TT® in adults aged 65 years and older in order to determine whether they respond differently than younger subjects.

11. MARKETING AUTHORISATION HOLDER (DETAILS OF MANUFACTURER)

Manufactured & marketed by:
Dano Vaccines & Biologicals Private Limited
Address: Sy. No. 575, Sivareddyguda, Ghatkesar, Medchal -Malkajgiri,501301, T.S., INDIA
Email: pv@danovaccines.com
Website: www.danovaccines.com
24 hrs helpline No: 1800 3096 009

12. DETAILS OF MARKETING AUTHORISATION NUMBER(S) (DETAILS OF PERMISSION OR LICENSE NUMBER WITH DATE)

Permission MF 145/2013 dated 08 July 2013 in form 46 under drugs & cosmetics act & rules 1945.

The first authorization for the manufacture of Tetanus Vaccine (Adsorbed) B.P. was granted on 28-Feb-1985 Under Manufacturing license no. 613/A.P. The present manufacturing license no. 05/RR/AP/95/CL/R for the manufacture of Tetanus Vaccine (Adsorbed) I.P.

13. DATE OF REVISION

Date of Revision: 18th May 2024
Revision No.: 4