SUMMARY OF PRODUCT CHARACTERISTICS

AbhayTOX®
[ATC Code: J07AM01]

December 2023

Manufactured by

HUMAN BIOLOGICALS INSTITUTE
(A Division of Indian Immunologicals Ltd.)
Rakshapuram, Gachibowli post,
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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Brand Name: AbhayTOX®

Generic Name: Tetanus vaccine (Adsorbed)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Tetanus Vaccine is a sterile suspension of Aluminium phosphate adsorbed tetanus toxoid in isotonic sodium chloride solution. The vaccine, after shaking, is a uniformly turbid liquid, whitish in colour.

Composition:

Each dose of 0.5 ml contains:

Tetanus Toxoid	5 to 25 Lf (≥ 40 IU)
Aluminium Phosphate ($AlPO_4$) as Al^{+++}	≤ 1.25 mg
Thiomersal (as preservative)	0.01 % w/v
Saline	q.s. to 0.5 ml

3. PHARMACEUTICAL FORM

Sterile suspension for intramuscular injection.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Active immunization against tetanus:

- For prevention of tetanus in all age groups following injury or animal bite.
- For prevention of neonatal tetanus in unvaccinated pregnant women.
- To persons who are at increased risk of attaining injuries through their occupational or recreational activities.

4.2. Posology and method of administration

DOSAGE:

AbhayTOX® vaccine is administered by intramuscular route.

A. Primary Immunization:

- **Standard Schedule:**

  The standard schedule is three primary doses of 0.5 ml of Tetanus vaccine at 6, 10 and 14 weeks and two boosters at 15-18 months and 5 years. Further booster doses with Tetanus vaccine are given at 10 years and 16 years and there after every 5 to 10 years. Single dose of Tetanus vaccine would suffice for subsequent pregnancies that occur in the next 5 years.

- **Schedule for individuals of 7 years of age and older:**

  Individuals 7 years of age and older who have not been immunized previously against tetanus, the primary immunization series of Tetanus vaccine consists of three doses given at intervals of 4 to 8 weeks between the first and second dose and 6 to 12 months between the second and third dose.

B. Immunization in pregnant women:

- **In non-immunized pregnant women:** Two doses of tetanus toxoid vaccine at least one month apart should be given for prevention of neonatal tetanus. The first dose should be administered at the time of first contact/ as early as possible and the second dose of tetanus vaccine should be administered 1 month later at least 2 weeks before delivery.

- **In previously immunized pregnant women:** One who has completed the full standard schedule 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.

C. Prophylaxis in injured persons:

The indications for Tetanus vaccine (TT) and Tetanus antisera/ Tetanus immunoglobulin (TIG) are as given below:

History of Tetanus Toxoid doses	**Clean minor wounds**		**All other wounds#**	
	TT	**Tetanus Antisera'/TIG''**	**TT**	**Tetanus Antisera'/TIG''**
Unknown or <3, immuno-deficient	Yes	No	Yes	Yes
≥ 3 doses	No*	No	No**	No

Including, but not limited to, wounds contaminated with dirt, feces, soil, saliva; puncture wounds; avulsions and wounds resulting from missiles, crushing, burns and frostbite.

' Tetanus Antisera 1500-5000 IU, IM (caution: 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).

'' TIG: Tetanus Immunoglobulin (250-500 IU, IM)

* Yes, If more than 10 years since last dose

** Yes, If more than 5 years since last dose

ADMINISTRATION:

Shake the vial to disperse the contents thoroughly immediately before withdrawing each dose of vaccine. A sterile disposable syringe and 24-gauge needle should be used for each injection.

The vaccine is administered deep intramuscularly in the anterolateral aspect of thigh in children and in the deltoid region in adolescents and adults. The vaccine should not be injected into gluteal area or areas where there may be a major nerve trunk.

4.3 Contraindications

- Hypersensitivity to any component of the vaccine.
- Anaphylaxis or other serious allergic reaction following a previous dose of this vaccine, any other tetanus toxoid containing vaccine or any component of this vaccine.
- Immunization should be deferred during the course of any febrile illness or acute infection. A minor febrile illness such as mild upper respiratory tract infection is not a contraindication.

4.4 Special warnings and precautions for use

WARNINGS:

- Tetanus vaccine should not be given more frequently than once in every 5 to 10 years for booster.
- For a person who has experienced severe Arthus type hypersensitivity reaction during the previous dose should not be administered with the vaccine more frequently than 10 years even if they have a bad wound.
- Tetanus vaccine should not be given to persons with any bleeding disorder, such as haemophilia or thrombocytopenia or to persons on anticoagulant therapy unless the potential benefits clearly outweigh the risk of administration.
- Pregnant women if infected with malaria, the transplacental transfer of antitoxin may be impaired.

PRECAUTIONS:

- An antihistamine may be indicated for mild allergic reactions.
- The vaccinated person should be observed for 30 to 60 minutes after administration of vaccine for any immediate reactions. This would help in

prompt management of the adverse/anaphylactic reaction, if any, and can be potentially reversed with proper and timely treatment.

- For anaphylactic reactions, adrenaline / epinephrine (1 in 1000) may be used. 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 (1ml). For infants and children the recommended dose of adrenaline is 0.01 mg/ kg (0.01ml/kg of 1:1000 injection). Single pediatric dose should not exceed 0.5 mg (0.5ml).
- Antihistamines, hydrocortisone IV fluids and other appropriate medications should also be used as per requirement.
- There is a chance of increased incidence of reactions to booster doses of Tetanus toxoid vaccine when given to previously immunized persons.
- Care should be taken to ensure that injection does not enter into a blood vessel.

4.5 Interactions with other medicinal products and other forms of interactions

- Routine vaccination should be deferred, if possible, in patients who are receiving immunosuppressive therapies including radiation, corticosteroids, antimetabolites, alkylating agents and cytotoxic drugs as they may reduce the immune response to vaccines.
- The vaccine can be safely and effectively given simultaneously with other vaccines if needed.
- As with other intramuscular injections, caution to avoid bleeding should be taken in patients on anticoagulant therapy.

4.6 Fertility, Pregnancy and Lactation

- *Pregnancy*:

  There is extensive human experience in the administration of Tetanus vaccine and there is no evidence of teratogenicity.
- *Lactation*:

  There is no information on the excretion of Tetanus vaccine antigens or antibodies in breast milk during breast-feeding.

4.7 Effects on ability to drive and use machines

Tetanus Toxoid vaccine (Adsorbed) - AbhayTOX®, is not reported to have any influence on the ability to drive and use machines.

4.8 Undesirable effects

AbhayTOX® is generally well tolerated. The following adverse events have been observed in clinical trial and during post marketing surveillance:

Local: Pain, tenderness, redness, swelling, induration, itching, warmth and rash.

Systemic: Fever, drowsiness, headache, pain in abdomen, diarrhea (loose motion), vomiting, myalgia, arthralgia, dysuria, URTI (upper respiratory tract infection).

The following additional adverse events have been documented involving use of similar Tetanus Toxoid vaccines as per published literatures:

Systemic: Hypotension, nausea, malaise.

Extremely Rarely:

Allergic/ hypersensitivity reactions including anaphylaxis, serum sickness, neurological complications including cochlear lesion, brachial plexus neuropathies, paralysis of the radial nerve, paralysis of the recurrent nerve, accommodation paresis and EEG disturbances with encephalopathy, Guillain-Barre syndrome (GBS).

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ATC-Code: J07AM01 (Vaccines, Bacterial vaccines, Tetanus toxoid)

Natural immunity *to Clostridium tetani* does not occur. The antigen present in tetanus vaccine is from the formaldehyde treated exotoxin of *Clostridium tetani*. Protection against disease is due to the development of neutralizing antibodies to tetanus toxin. Injection of tetanus toxoids results in the production of protective antibodies. The peak antibody levels achieved with the first dose are usually low, and a primary series is required to prime the immune system and produce a high antibody level. Response to Tetanus toxoid: The subjects are considered protected if the antibody levels are ≥ 0.1 IU/ml.

A total of 378 subjects healthy subjects between 10 to 55 years of age recruited in a clinical trial received a single intramuscular dose of Tetanus Toxoid (Adsorbed) vaccine. The pre and the post vaccination geometric mean titers (GMT) were 1.06 IU/ml and 8.87 IU/ml respectively. Pain, redness, swelling, tenderness, induration and itching were the local adverse events reported. Similarly the systemic adverse events reported were fever, headache, body pain (myalgia), drowsiness, pain in

the abdomen, diarrhea (loose motion), vomiting, joint pain (arthralgia), dysuria and URTI (upper respiratory tract infection). No serious adverse event was reported in the clinical trial.

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Preclinical toxicology study of AbhayTOX® concluded that the vaccine is safe for use at the recommended human dose.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

- Aluminium phosphate
- Thiomersal
- Saline

6.2. Incompatibilities

AbhayTOX® vaccine must not be mixed with other vaccine(s), Anti Tetanus Serum or any other medicinal product(s) in the same syringe.

6.3. Shelf life

Three years from the date of manufacture (when stored at recommended conditions including temperature).

6.4. Special precautions for storage

- Protect from light.
- Do not freeze.
- Discard vial if contents are frozen.
- AbhayTOX® must be stored and transported between $+2^{o}$ C and $+8^{o}$ C.
- Once opened, multi-dose vials should be kept between $+2^{o}$ C and $+8^{o}$ C. Multi-dose vials of Tetanus vaccine from which one or more doses of vaccine have 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 vaccines are stored under appropriate cold chain conditions.
    - The vaccine vial septum has not been submerged in water.
    - Aseptic techniques have been used to withdraw all doses.
    - The vaccine vial monitor (VVM), has not reached the discard point.

6.5. Nature and contents of container

- Combo pack: contains single dose of 0.5 ml Tetanus vaccine, sterile disposable syringe with needle and alcohol swab.
- Single-dose vial of 0.5 ml.
- Multi-dose vial of 2.5ml and 5 ml.

6.6. Special precautions for disposal and other handling

(A) Disposal:

As per the applicable Biomedical Waste Disposal guidelines/ rule.

(B) Other Handling:

- Shake well before use.
- Discard if vaccine cannot be re-suspended.
- AbhayTOX® must not be diluted to administer.
- Use new sterile syringe and needle for every administration.
- Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine.

7. MARKETING AUTHORISATION HOLDER

Human Biologicals Institute

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Rakshapuram, Gachibowli Post,
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Web:www.indimmune.com

8. MARKETING AUTHORISATION NUMBER

The Marketing Authorization Number is country specific. In India, the country of origin, the Marketing Authorization Number is: 02/RR/AP/2005/V/R.

9. DATE OF FIRST AUTHORISATION

Date of First Authorization in India, the country of origin is: 23.01.2007.

10. DATE OF COMPILATION OF THE TEXT

December 2023