SUMMARY OF PRODUCT CHARACTERISTICS

DIPHTHERIA AND TETANUS VACCINE (ADSORBED) FOR ADULTS AND ADOLESCENTS (Td) I.P.

(ATC-Code: J07AM51)

August 2024

Manufactured by

HUMAN BIOLOGICALS INSTITUTE
(A division of Indian Immunologicals Ltd)
Rakshapuram, Gachibowli Post,
Hyderabad-500032, Telangana, India.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Brand Name: TeddyVac

Generic Name: Diphtheria and Tetanus (Td) vaccine (Adsorbed)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Diphtheria and Tetanus vaccine (Adsorbed) for Adults and Adolescents (Td vaccine) is a whitish turbid suspension of Diphtheria toxoid and Tetanus toxoid adsorbed on Aluminium phosphate, which is used as adjuvant. Thiomersal is added as preservative.

Composition:

Each single human dose of 0.5 ml contains:

Diphtheria Toxoid	≥ 2 IU (≤ 5 Lf)
Tetanus Toxoid	≥ 20 IU (≥ 5 Lf)
Aluminium Phosphate as Al^{+++}	≤ 1.25mg
Thiomersal (as preservative)	0.01% w/v
Saline	q.s. to 0.5ml

(*For full list of excipients, see section 6.1*)

3. PHARMACEUTICAL FORM

Liquid suspension for intramuscular injection.

- 1 dose vial of 0.5 ml
- 10 dose vial of 5 ml

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- It is indicated as a booster dose to children after a primary immunization course with DTP containing vaccine.
- It can also be used in all age groups replacing the TT vaccine.
- Td vaccine may be used as a primary immunization for persons from 7 years of age who have not received primary immunization course with DTP containing vaccine.

4.2 Posology and method of administration

Posology:

A single dose consists of 0.5 ml.

This Td vaccine is indicated as a booster dose to children of 10 years and 16 years of age after a primary immunization course with DTP containing vaccine. Thereafter, booster doses can be administered every 10 years. However, a minimum interval of at least one year between doses should be maintained.

Td vaccine may be used as a primary immunization for persons from 7 years of age. They should receive two doses of 0.5 ml of the vaccine at an interval of at least four weeks. A third dose is recommended at least 6 months after the second dose.

Method of administration:

The vaccine vial should be gently shaken before use to homogenize the suspension. The vaccine should be administered intramuscularly, the site of injection preferably being deltoid muscle. The vaccine should not be injected subcutaneously, intradermally or intravenously.

A sterile needle and syringe should be used for each injection. The site of administration must be sterilized by cotton soaked in rectified spirit or alchol swab which should be allowed to evaporate before injection.

Another injection, if co-administered with Td Vaccine, should be administered at a different site.

Once opened, multi-dose vials should be kept between +2°C and +8°C. Multi-dose vials of Td vaccine 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:

- 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 technique has been used to withdraw all doses;

The vaccine should be visually inspected for any foreign particulate matter and/ or variation of physical aspect prior to administration. In the event of either being observed, the vaccine should be discarded immediately as per the applicable biomedical waste disposal guideline.

4.3 Contraindications

- It is contraindicated in case of known hypersensitivity to any component of the vaccine.

- The vaccine should not be administered to persons who showed any severe reaction to a previous dose of Diphtheria and Tetanus vaccine.
- A history of systemic allergic or neurologic reactions following a previous dose of the vaccine is an absolute contraindication for further use.
- Immunization should be deferred during the course of an acute illness. Vaccination of persons with severe febrile illness should generally be deferred until these persons have recovered. However, the presence of minor illnesses such as mild upper respiratory infections with or without fever is not a contraindication for further use.

4.4 Special warnings and precautions for use

Warnings:

- The vaccine should not be administered more frequently than once in every 10 years for booster.
- 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.
- The vaccine should be administered with caution 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.

Precautions:

- Prior to an injection of any vaccine, all known precautions should be taken to prevent adverse reactions. This includes a review of any previous adverse reactions to the vaccine or similar vaccines, previous immunization history, current health status and a current knowledge of the literature concerning the use of the vaccine under consideration. Immunosuppressed persons may not respond to vaccination.
- Special care should be taken to ensure that the needle does not enter a blood vessel during administration.
- 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 adult dose should not exceed 1 mg (1 ml). For 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 (0.5 ml). The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be lifesaving.
- As with the use of all vaccines, the vaccinee should remain under observation for not less than 30 minutes for possibility of occurrence of immediate or early allergic reactions. This would help in prompt management of the adverse reaction, if any, and can be potentially reversed with proper and timely treatment.
- Antihistamines, hydrocortisone, IV fluids, oxygen inhalation and other appropriate medications should be available and used as per requirement.

- Syncope can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury in such scenario.

4.5 Interaction with other medicinal products and other forms of interaction

- If Td vaccine and Tetanus immunoglobulin or Diphtheria Antitoxin are administered concurrently, separate needles, syringes and separate sites should be used. As with other intramuscular injections, it should be used with caution in patients on anticoagulant therapy.
- Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids used in greater than physiologic doses may reduce the immune response to vaccines.

4.6 Fertility, Pregnancy and Lactation

- Diphtheria and Tetanus (Td) vaccine (Adsorbed) has not been evaluated for its effect on fertility.
- The effect of Diphtheria and Tetanus (Td) vaccine (Adsorbed) in pregnant women has not been studied.
- The effect on breast-fed infants of the administration of Diphtheria and Tetanus (Td) vaccine (Adsorbed) to their mothers has not been studied.

4.7 Effects on ability to drive and use machines

No data is available.

4.8 Undesirable effects

Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents (Td vaccine) is generally well tolerated. The following adverse events have been observed in clinical trials of the vaccine:

- **Local:** Pain, redness, swelling and pruritus at the site of injection.
- **Systemic:** Fever, malaise, myalgia, headache.

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

- **Local:** tenderness, induration, sterile abscess.
- **Systemic:** feverishness, fatigue (tiredness), irritability, nausea, diarrhoea, gastrointestinal symptoms, arthralgia.

In addition, the following may also be considered as potential rare undesirable effects based on scientific literature:

- Erythema multiforme, arthritis
- Arthus-type hypersensitivity reactions, characterized by severe local reactions (generally starting 2 to 8 hours after an injection) may occur, particularly in

persons who have received multiple prior booster doses of a Tetanus Toxoid containing vaccine. Rarely anaphylaxis may also occur.

- The following neurologic illnesses have been reported as temporally associated with Tetanus Toxoid containing vaccines: neurological complications including cochlear lesion, brachial plexus neuropathies, paralysis of the radial nerve, paralysis of the recurrent nerve, accommodation paresis, EEG disturbances with encephalopathy. There is biologic plausibility of possible association between Tetanus Toxoid containing vaccines and demyelinating disorders like Guillain-Barre Syndrome (GBS).

4.9 Overdose

There has been no report of overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

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- Administration of Diphtheria and Tetanus Vaccine (Adsorbed) stimulates the immune system of the body. The immune response thus elicited includes production of protective antibodies against Diphtheria and Tetanus in the body. The humoral immune response is considered seroprotective when anti-diphtheria antibody (IgG) titre of ≥ 0.1 IU/mL and anti-tetanus antibody (IgG) titre of ≥ 0.1 IU/mL are achieved.

- In Phase II/III clinical trial conducted in India, immunogenicity and safety of a single dose of the vaccine were studied in two age groups of healthy subjects: 148 subjects in the age group of 18 years to 60 years (Group A) and 148 subjects from 10 years to below 18 years of age (Group B). The overall Seroprotection rate post vaccination for tetanus component was 100% whereas the same for the Diphtheria component was 98.6%. There was a significant rise in GMT (Geometric Mean Titres) post vaccination in comparison to pre-vaccination titres for both Tetanus and Diphtheria components for both the age groups. The overall post vaccination GMT for Tetanus component was 11.54 IU/mL whereas for Diphtheria component, it was 1.29 IU/ mL. No Serious adverse event (SAE) was reported during the study. Among the Local adverse events, Injection site pain (15.5%) was the most common adverse event followed by Injection site swelling (2.7%), Injection site erythema (0.7%) and Injection site pruritus (0.3%). Among the systemic adverse events, Myalgia (1.7%) was the most common adverse event followed by Pyrexia (0.7%), Headache (0.7%), Malaise (0.3%) and Vomiting (0.3%). The severity grading for majority of adverse events was mild and for a very few it was moderate.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Preclinical toxicology study of the Diphtheria and Tetanus vaccine (Adsorbed) concluded that the vaccine is safe for use at the recommended human dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Aluminium phosphate
- Thiomersal
- Sodium Chloride

6.2 Incompatibilities

- The Td vaccine must not be mixed with other vaccines or any other medicinal product(s) in the same syringe.

6.3 Shelf life

- 36 months from the date of manufacture, when stored in recommended storage conditions.

6.4 Special precautions for storage

- Keep out of reach of Children.
- Store and transport between +2° C and +8° C.
- DO NOT FREEZE. Discard if frozen.
- Shake well before use.
- Do not keep the vaccine along with other medicinal product including other vaccine(s) that could create confusion and lead to admixture.

6.5 Nature and contents of container

Diphtheria and Tetanus vaccine (Adsorbed) is supplied as a liquid formulation in a glass vial.

6.6 Special precautions for disposal and other handling:

A) Disposal:

Any unused product or waste material should be disposed as per the applicable biomedical waste disposal guideline.

B) Other Handling:

- Gently shake well to get a uniform suspension before use.
- Discard if vaccine cannot be re-suspended.
- Use 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.

- Do not use if precipitation is observed.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

MF/BIO/22/000078 dated 25-Aug-2022.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of First Authorisation: 25-Aug-2022.

10. DATE OF REVISION OF THE TEXT

August 2024

11. REFERENCES:

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