SUMMARY OF PRODUCT CHARACTERISTICS

Teddyvac™

(ATC-Code: J07AM51)

December 2023

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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Brand Name: Teddyvac™

Generic Name: Diphtheria and Tetanus (Td) vaccine (Adsorbed) for Adults and Adolescents I.P.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Each single human dose of 0.5 ml contains:

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

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

3. PHARMACEUTICAL FORM

Liquid suspension for intramuscular injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For active immunization against Diptheria and Tetanus in adolescents (10years to below 18 years) &Adults (Age 18years to 60years).

4.2 Posology and method of administration

Posology:

A single dose consists of 0.5 ml.

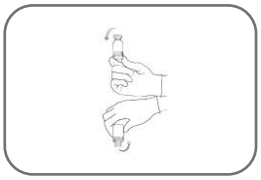
This Td vaccine is indicated as a booster dose to children of 10 years and 16 years of age after a primary immunization course with DTP containing vaccine.
Thereafter, booster doses can be administered to individual up to 60years of age as and when indicated in place of Tetanus toxoid vaccine.

Method of administration:

The vaccine vial should be gently shaken before use. The vaccine should be injected intramuscularly. The preferred for injection is deltoid muscle. care should be taken not to inject subcutaneously, intradermally or intravenously.

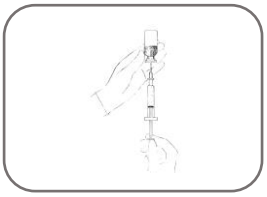
only sterile syringe and needle should be used for each injection. The site of administration must be sterilized by cotton soaked in rectified spirit or alchol swab which should be allowed to evaporate before injection.

1



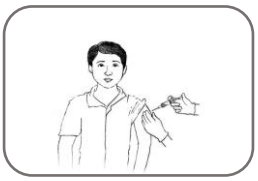
Mixing of the content of the vial before withdrawal into syringe

2



Withdrawal of the vaccine into the syringe before administration

3



Intramuscular Administration in Deltoid muscle

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.
- Another injection if Co-administered with Td vaccine, should be administered at a different site.
- 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

- 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:** injection site Pain, injection site erythema (redness), injection site swelling and injection site pruritus.
- **Systemic:** Pyrexia (Fever), malaise, myalgia, headache and Vomiting.

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

- **Local:** tenderness, induration, sterile abscess at the site of injection.
- **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

No data is available.

5. PHARMACOLOGICAL PROPERTIES

Mechanism of Action

Administration of Diphtheria and Tetanus Vaccine (Adsorbed) results in the production of protective antibodies against Diphtheria and Tetanus.

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Vaccines, Combined vaccines

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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 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 titre 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
- Saline

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 at 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.
- In case of vaccine vials with vaccine vial monitor (VVM) the following has to be checked for decision regarding use/ discard of the vial:

The vaccine vial monitor (VVM), has not reached the discard point. if:

✓ Inner Square lighter than outer circle.

If the expiry date has not been passed USE the vaccine.

✓ At a later time, inner square still lighter than outer circle

If the expiry date has not been passed USE the vaccine.

The vaccine vial monitor (VVM), has reached the discard point, if:

× Inner Square matches colour of outer circle

DO NOT use the vaccine.

The vaccine vial monitor (VVM), has crossed the discard point, if:

× Inner Square is darker than outer ring.

DO NOT use the vaccine.

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

HUMAN BIOLOGICALS INSTITUTE
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Rakshapuram, Gachibowli Post,
Hyderabad-500032, Telangana, India.
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/RENEWAL OF AUTHORISATION

Date of First Authorization in India, the country of origin: February 2023.

10. DATE OF REVISION OF THE TEXT

December 2023.