1. NAME OF THE MEDICINAL PRODUCT

Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P.

Injectable, Suspension for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 ml contains:

Diphtheria Toxoid	≤ 5 Lf (≥ 2 IU)
Tetanus Toxoid	≥ 5 Lf (≥ 40 IU)
Adsorbed on Aluminium Phosphate, Al^{+++}	≤ 1.25 mg

Preservative 0.005% Thiomersal

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Diphtheria and tetanus vaccine adsorbed (Td) for adults and adolescents has the appearance of a greyish - white suspension and does not contain any horse serum protein.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The vaccine is recommended for use in primary vaccination and revaccination of adults and adolescents who are having contraindications of Diphtheria, Tetanus and Pertussis (DTP). Primary vaccination and revaccination of children older than 7 years. In order to prevent allergic reactions to the protein of Diphtheria toxoid, the quantity of the toxoid has been markedly reduced.

After a primary immunization course of either DTP or Td vaccine, adsorbed Td vaccine for adults may be used as a booster at intervals of approximately 10 years, but with a minimum of at least one year between doses. It can safely replace monovalent tetanus toxoid (TT) vaccine, including during pregnancy.

The vaccine can be safely and effectively given simultaneously with BCG, Measles, Polio Vaccine (IPV and OPV), Hepatitis - B and Yellow fever Vaccine.

4.2 Posology and method of administration

Posology:

Two injections of 0.5 ml at least four weeks apart followed by a third injection 6 to 12 months after the second dose. The vaccine should also be given as a booster immunization every 5 to 10 years.

Administration:

The vaccine should be injected intramuscularly. The preferred site for injection is deltoid muscles. Care should be taken not to inject into the blood vessel or the skin. Only sterile syringes and needles should be used for each injection. The vaccine should be well shaken before use. Once opened, multi-dose vials should be kept between 2°C to 8°C. Multi-dose vials of Td vaccine from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for upto a maximum of 28 days provided that all of the following conditions are met (as described in the WHO policy statement: Handling of multi dose vaccine vials after opening, WHO/IVB/14.07):

- The vaccine is currently prequalified by WHO;
- The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO;
- The expiry date of the vaccine has not passed; The vaccine vial has been, and will continue to be, stored at WHO - or manufacturer recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

The vaccine should be visually inspected for any foreign particulate matter and / or variation of physical aspect prior to administration. In event of either being observed, discard the vaccine.

4.3 Contraindications

The vaccine should not be given to persons who showed a severe reaction to a previous dose of Diphtheria and Tetanus vaccine.

A history of systemic allergic or neurologic reactions following a previous dose of Td 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 should not preclude vaccination.

4.4 Special warning and precautions for use

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 mg - 0.5 mg (0.1 ml - 0.5 ml of 1:1000 injection) given s/c or i/m. Single dose should not exceed 1 mg (1 ml). For children the recommended dose of adrenaline is 0.01 mg/kg (0.01 ml/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. It should be used at the first suspicion of anaphylaxis.

As with the use of all vaccines the vaccinees should remain under observation for not less than 30 minutes for possibility of occurrence of immediate or early allergic reactions. Hydrocortisone and anti-histaminics should also be available in addition to supportive measures such as oxygen inhalation.

Special care should be taken to ensure that the injection does not enter a blood vessel.

It is extremely important when the parent, guardian or adult patient returns for the next dose in the series, the parent, guardian or adult patient should be questioned concerning occurrence of any symptoms and / or signs of an adverse reaction after the previous dose.

HIV Infection:

Diphtheria and tetanus vaccine (Adsorbed) for adults and adolescents may be used in adults and adolescents with known or suspected HIV infection. Although the data are limited and further studies are being encouraged, there is no evidence to date of any increased rate of adverse reactions using this vaccine in symptomatic or asymptomatic HIV infected adults and adolescents.

4.5 Interaction with other medicinal products and other forms of Interaction

If Td and Tetanus Immunoglobin or Diphtheria Antitoxin is administered concurrently, separate syringes and separate sites should be used.

As with other intramuscular injections, use with caution in patients on anticoagulant therapy. Immunosuppressive therapies, including irradiation, anti-metabolites, alkylating agents, cytotoxic drugs, and corticosteroids used in greater than physiologic doses may reduce the immune response to vaccines.

4.6 Pregnancy and lactation

Td vaccine is safe to be administered to pregnant women. Infact, it is recommended in pregnant women, for prophylaxis against neonatal tetanus.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Reactions are generally mild and confined to the site of injection. Some inflammation may occur together with transient fever, malaise and irritability. Occasionally a nodule may develop at the site of injection but this is rare.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccines

Tetanus toxoid, combinations with diphtheria toxoid, ATC code J07AM51.

Immunological Data:

Clinical trials performed to assess immunogenicity and reactogenicity of the vaccine proved that the vaccine is immunogenic.

In a study in Hyderabad, in 706 children in the age group of 7 to 17 years, 98% and 94.7% children were protected following vaccination and 88% and 65.1%showed long term protection for tetanus and diphtheria, respectively.

In a phase IV study of Td vaccine in 62 adults aged more than 30 years, the seroprotection for diphtheria increased from 88% before vaccination to 100% following vaccination, while 100% subjects had seroprotection before as well as after vaccination

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Phosphate (Prepared from Aluminium chloride + Tri-sodium phosphate)

Thiomersal

Sodium chloride

Sodium Acetate

Water for Injection

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

36 months from the date of manufacturing.

6.4 Special precautions for storage

The vaccine should be stored in a dry, dark place at a temperature between 2°C to 8°C. Transportation should also be at 2°C to 8°C. DO NOT FREEZE.

6.5 Nature and contents of container

Single dose presentation: 1 dose pre-filled syringe of 0.5 ml

1 dose ampoule of 0.5 ml

1 dose vial of 0.5 ml

Multi-dose presentation: 10 dose vial of 5 ml

20 dose vial of 10 ml

6.6 Special precautions for disposal

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

7. MARKETING AUTHORISATION HOLDER / PREQUALIFICATION HOLDER

Name: Serum Institute of India Pvt. Ltd.

Address: 212/2, Hadapsar, Pune - 411 028, Maharashtra, INDIA.

Telephone No: +91-20-26993900

Fax No: +91-20-26993921

E-mail: contact@seruminstitute.com

8. MARKETING AUTHORISATION NUMBER(S)

Permission No. - MF/BIO/19/000014

Manufacturing License No. 10 in Form 28-D

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

S/N	Approved as	Product Approval date
1.	Diphtheria and Tetanus Vaccine Adsorbed for Adults and Adolescents, meeting WHO requirements	05.06.1995
2.	Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P.	23.08.2008
3.	Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P. in pre-filled syringe	24.07.2008
4.	Marketing Authorization Regularization	16.04.2019

Date: 31 December 2022