

1. NAME OF THE MEDICINAL PRODUCT

Diphtheria and Tetanus Vaccine (Adsorbed) I.P.

Injectable, Suspension for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 ml contains:

Diphtheria Toxoid	≤ 25 Lf (≥ 30 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

Suspension for injection.

Whitish turbid uniform suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Diphtheria and Tetanus vaccine (adsorbed) is indicated for the primary immunization of infants, at or above the age of two months and of pre-school children against diphtheria and tetanus in whom simultaneous immunization against pertussis is not indicated.

4.2 Posology and method of administration

Posology:

Three injections of 0.5 ml each at least four weeks apart followed by a fourth dose 6 to 12 months later.

For primary immunization of infants and pre-school children it is recommended that three intramuscular injections of 0.5 ml be administered with an interval of four to eight weeks between doses. A fourth injection of 0.5 ml should be administered intramuscularly approximately one year after initial injection.

Although it is recommended that immunization be started at two to six months of age, if for any reason it is delayed, the same schedule may be used throughout the pre-school period.

A reinforcing injection of 0.5 ml intramuscularly should be administered between four and six years of age (i.e. at the time of school entry).

Administration:

The vaccine should be injected intramuscularly. The preferred site for injection in infants and young children is the anterolateral aspect of the upper thigh or the deltoid muscle in older children.

Only sterile needles and syringes should be used for each injection. The vaccine should be well shaken before use.

Each injection of the primary immunization series should be made into a different site.

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

Diphtheria and Tetanus Vaccine (Adsorbed) should not be administered to infants or children with high fever, or other evidence of acute illness.

Elective immunization of individuals over six months of age should be deferred during an outbreak of poliomyelitis.

Diphtheria and Tetanus Vaccine (Adsorbed) should not be administered to older children (after six years of age) or to adults because of the danger increased risk of reactions to diphtheria toxoid.

The specific contraindications adopted by individual national health authorities should reflect a balance between the risk from the vaccine and the risk from the disease. Because the risk from the vaccine remains extremely low in comparison to the risk from the disease in many developing countries, authorities there may choose to offer immunization to children who are mildly to moderately ill or malnourished.

4.4 Special warnings and precautions for use

Individuals receiving corticosteroids or other immunosuppressive drugs may not develop an optimum immunologic response.

The possibility of allergic reactions in individuals sensitive to the components of the product should be borne in mind.

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 dose should not exceed 1 mg (1 ml). For infants and children the recommended dose of adrenaline is 0.01 mg/kg (0.01 ml/kg of 1:1000 injection). Single paediatric dose should not exceed 0.5 mg (0.5ml). 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 antihistaminics 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, or guardian, returns for the next dose in the series, the parent, or guardian, should be questioned concerning occurrence of any symptoms and/or signs of an adverse reaction after the previous dose.

Frequent booster doses of tetanus toxoid in the presence of adequate or excessive serum levels of tetanus antitoxin have been associated with increased incidence and

severity of reactions and should be avoided. If hypersensitivity to the diphtheria component is suspected tetanus toxoid should be used for reinforcing doses.

A separate sterile syringe and needle 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

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

No clinical data on use during pregnancies are available with this vaccine as this vaccine is intended for use in paediatric population (< 6 years of age) only.

4.7 Effects on the ability to drive and use machines

No data available on effects on the ability to drive and use machines for this vaccine as this vaccine is intended for use in paediatric population only.

4.8 Undesirable effects

Mild local reactions consisting of pain, erythema, tenderness and induration at the injection site are common 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 an adsorbed vaccine, but this complication is unusual.

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 Jalna, India, in 244 children in age group of 4-6 years, 0.5 ml of DT vaccine was administered in a dose of 0.5 ml in the deltoid muscle. Seroprotection for diphtheria increased significantly from 70% before vaccination to 98% at 28 days following DT vaccination. Also, seroprotection for tetanus increased significantly from 86% before vaccination to 100% at 28 days following DT vaccination.

5.2 Pharmacokinetic properties

Pharmacokinetic studies are not required for vaccines.

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/20/000095 in Form 46.

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) I.P.	06.04.1991
2.	Diphtheria and Tetanus Vaccine Adsorbed (Paediatric), meeting WHO requirements	05.06.1995
3.	Diphtheria and Tetanus Vaccine (Adsorbed) I.P. in pre-filled syringe	24.07.2008
4.	Marketing Authorization Regularization	10.12.2020

Date: 31 December 2022