

	Serum Institute of India Pvt. Ltd.	SUMMARY OF PRODUCT CHARACTERISTICS Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) I.P.
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1. NAME OF THE MEDICINAL PRODUCT

Diphtheria, Tetanus and Pertussis 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)
B. pertussis	≤ 16 OU (≥ 4 IU)
Adsorbed onto 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.

Greyish - white suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the primary immunization of infants at or above the age of six weeks and of children through six years of age against diphtheria, tetanus and whooping cough.

4.2 Posology and method of administration

Posology:

For the purpose of primary immunization it is recommended that 3 doses each of 0.5 ml should be inoculated on 3 separate occasions at 4 weeks interval. The first dose should be given at approximately 6 weeks of age. Reinforcing injections of 0.5 ml should be given 12 months after the primary immunization and also between the ages of 4 to 6 years.

Although it is recommended that immunization to be started at 6 weeks, if for any reason it is delayed, the same schedule may be used up to the sixth birthday. 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). This booster dose is not necessary if the fourth primary immunizing dose has been administered after the fourth birthday.

Administration:

DTP vaccine should be administered by deep intramuscular injection. The anterolateral aspect of the upper thigh is the preferred site of injection. Only sterile needles and syringes should be used for each injection. The vaccine should be well shaken before use.

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Each injection of the primary immunization series should be made into a different site with a sterile disposable syringe and needle. 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.

How to use SII DTP vaccine and SII Hib vaccine as Quadravalent

SII DTP to be used to reconstitute SII Hib vaccine for simultaneous administration via single injection. SII Hib vaccine must be reconstituted by adding the entire contents of SII DTP ampoules or 0.5 ml of SII DTP from a multi dose vial of SII DTP. After the addition of SII DTP to Hib pellet, the mixture should be well shaken until the Hib pellet is completely dissolved in the SII DTP suspension. After reconstitution the combined vaccine should be injected promptly. Inject 0.5 ml suspension by intramuscular injection.

4.3 Contraindications

Known hypersensitivity to any component of vaccine, or a severe reaction to previous dose of the vaccine or any of its constituents is an absolute contraindication to subsequent doses of the vaccine or the specific vaccine known to have provoked an adverse reaction. There are few contraindications to first dose of DTP. Fits or abnormal cerebral signs in the newborn period or other serious neurological abnormality are contraindications to the pertussis component. In this case DT should be given instead of DTP vaccine.

4.4 Special warnings and precautions for use

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

This product should be used only for infants and children from 6 weeks through six years of age. The possibility of allergic reactions in individuals sensitive to the components of the vaccine 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 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. Hydrocortisone and antihistaminics should also be available in addition to supportive measures such as oxygen inhalation. 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.

DTP VACCINE (ADSORBED) SHOULD BE GIVEN ONLY FOR INFANTS AND CHILDREN THROUGH SIX YEARS OF AGE.

IMMUNE DEFICIENCY

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Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with DTP vaccine according to standard schedules.

4.5 Interaction with other medicinal products and other forms of interaction

If DTP and TIG 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

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

4.8 Undesirable effects

Mild, local reactions are common. Some temporary swelling, tenderness and redness at the site of injection together with fever occur in large proportion of cases. Occasionally severe reactions of high fever, irritability and screaming develop within 24 hours of administration. Hypotonic-hypo responsive episodes have been reported. Febrile convulsions have been reported rarely. Administration of paracetamol at the time of and 4-8 hours after immunization decreases the subsequent incidents of febrile reactions. The national childhood encephalopathy study in the United Kingdom showed a small increases risk of acute encephalopathy (primarily seizures) following DTP immunization. However subsequent detailed reviews of all available studies by a number of groups, including the United States Institute of Medicine, the Advisory Committee of Immunization Practices, and the pediatric association of Australia, Canada the United Kingdom, and the United States concluded that the data did not demonstrate the causal relationship between DTP and chronic nervous system dysfunction in children. Thus there is no scientific evidence that hypotonic-hypo responsive episode and febrile convulsions have any permanent consequences for the children.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccines

Pertussis, inactivated, whole cell, combinations with toxoid, ATC code J07AJ51.

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Immunological Data:

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

In a multicentric trial in India, 0.5 ml of DTP vaccine was administered to 166 healthy infants at 6, 10 and 14 weeks. Following vaccination, the seroprotection for diphtheria and tetanus was 98.62% and 100%, respectively, and the seropositivity for pertussis was 95.86%.

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

24 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 - 8°C. Transportation should also be at 2°C - 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 : 2 dose ampoule of 1 ml
2 dose vial of 1 ml
5 dose vial of 2.5 ml
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.

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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

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E-mail: contact@seruminstitute.com

8. MARKETING AUTHORISATION NUMBER(S)

Manufacturing License No. 10 in Form 28-D

Permission No. - MF/BIO/21/000003 in Form 46.

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

S/N	Approved as	Product Approval date
1.	Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) I.P.	06.04.1991
2.	Diphtheria-Tetanus-Pertussis Vaccine Adsorbed, meeting WHO requirements	05.06.1995
3.	Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) I.P. in pre-filled syringe	24.07.2008
4.	Marketing Authorization Regularization	04.01.2021

License Retention: 01.01.2022

Date: 31 December 2022