1. NAME OF THE MEDICINAL PRODUCT

Diphtheria-Tetanus-Pertussis Vaccine Adsorbed

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single 0.5 ml human dose contains:

Diphtheria Toxoid	≤ 25 Lf (≥ 30 IU)
Tetanus Toxoid	≥ 5 Lf (≥ 40 IU)
B. pertussis vaccine	≤ 16 OU (≥ 4 IU)
Adsorbed on Aluminum Phosphate, Al^{+++}	≤ 1.25 mg
Preservative: Thiomersal	0.005 %

3. PHARMACEUTICAL FORM

Suspension for injection

Whitish turbid liquid

4. CLINICAL PARTICULARS

4.1 Indications:

For the primary immunization of infants, above the age of six weeks, and of pre-school children against diphtheria, tetanus and whooping cough. The vaccine can be safely and effectively given simultaneously with BCG, Measles, Polio vaccines (IPV and OPV), Hepatitis B, Yellow fever Vaccine, Haemophilus influenzae type b, Varicella vaccine and vitamin A supplementation.

4.2 Posology and method of administration

Dosage:

For the purpose of primary immunization it is recommended that 3 doses of 0.5 ml should be inoculated on 3 separate occasions at 4 to 6 week intervals. 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.

Administration:

DTP vaccine should be injected intramuscularly. The anterolateral aspect of the upper thigh is the preferred site of injection. (An injection into a child's buttocks may cause injury to the sciatic nerve and is not recommended). It must not be injected into the skin as this may give rise to local reaction. Only sterile needles and syringes should be used for each injection. The vaccine should be well shaken before use.

Once opened, multi-dose vials should be kept between +2ºC and +8ºC. Multi-dose vials of DTP 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 (as described in the WHO policy statement: handling of multi dose vaccine vials after opening WHO/IVB/14.07):

- The expiry date has not passed;
- 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 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:

Known hypersensitivity to any component of the vaccine, or a severe reaction to a 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 the 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.

Immunization should be postponed if the infant has an acute disease. However, low grade fever, mild respiratory infections, malnutrition or diarrhea should not be considered as contraindications. Infants who have active or progressive neurological disease including recent convulsions should not be given pertussis- containing vaccines. Adsorbed DT vaccine should be given instead. A second or subsequent dose of DTP vaccine should not be given to

a child who had a severe reaction like persistent screaming, shock, convulsions or encephalopathy to the previous dose. Adsorbed DT vaccine should be given for the remainder of the course.

4.4 Special warnings and precautions for use

Precautions:

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. It should be used at the first suspicion of anaphylaxis.

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.

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.

4.5 Interaction with other medicinal products and other forms of Interaction

Drug Interactions

If DTP and TIG or Diphtheria Antitoxin are 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, 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

Not Applicable (for pediatrics)

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Mild local or systemic reactions are common. Some temporary swelling, tenderness and redness at the site of injection together with fever occur in a large proportion of cases. Occasionally severe reactions of high fever, irritability and screaming develop within 24 hours of administration. Hypotonichyporesponsive episodes have been reported. Febrile convulsions have been reported at a rate of one per 12500 doses administered. Administration of paracetamol at the time of and 4-8 hours after immunization decreases the subsequent incidence of febrile reactions. The national childhood encephalopathy study in the United Kingdom showed a small increased 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 on Immunization Practices, and the paediatric associations of Australia, Canada, the United Kingdom and the United States, concluded that the data did not demonstrate a causal relationship between DTP and chronic nervous system dysfunction in children. Thus there is no scientific evidence that hypotonichypo responsive episode and febrile convulsions have any permanent consequences for the children.

IMMUNE DEFICIENCY

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

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccines
ATC code J07AJ51

5.2 Pharmacokinetic Properties

Not applicable for vaccine

5.3 Preclinical safety data

No data available

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Aluminium Phosphate (Prepared from Aluminium chloride, Sodium Chloride, Sodium Acetate Trihydrate and Trisodium phosphate Dodecahydrate)

Thiomersal

Water for Injection

6.2 Incompatibilities

This product must not be mixed with other medicinal products.

6.3 Shelf life

30 Months from the date of manufacture.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

1 Dose Ampoule	Clear white tubular type I glass ampoule with One Point Cut (OPC) mechanism
10 Dose Vial	Clear white tubular type I glass vial; sealed with rubber stopper and flip-off seal
20 Dose Vial	Clear white tubular type I glass vial; sealed with rubber stopper and flip-off seal

Note: All pack sizes may not be marketed.

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

Serum Institute of India Pvt. Ltd.
212/2, Hadapsar, Pune-411028, INDIA.

8. MARKETING AUTHORISATION NUMBER(S)

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10. DATE OF REVISION:

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