SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Product Name: Diphtheria, Tetanus and Whole cell Pertussis Vaccine (Adsorbed) IP

Brand Name: DTwP

Strength: One pediatric dose is 0.5 ml

Pharmaceutical Form: Injectable Vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 ml contains:

Component	Quantity per dose of 0.5 ml
Diphtheria Toxoid	20 Lf (30IU)
Tetanus Toxoid	7.5 Lf (60 IU in mice and 40 IU in guinea pigs)
Pertussis Vaccine (Whole Cell)	12 OU (4 IU)
2-Phenoxyethanol	2.5 mg
Aluminium content (Al^{3+})	0.25 mg
Physiological saline	q.s

3. PHARMACEUTICAL FORM

Suspension for Intramuscular Injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The vaccine is indicated for active immunization against Diphtheria, Tetanus and Pertussis in infants from 6 weeks onwards.

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4.2 Posology and method of administration

The recommended dose (0.5 ml) of the vaccine must be administered. The primary vaccination schedule consists of three doses within the first six months of life at intervals of at least 4 weeks. The administration of a booster dose with DTP vaccine is recommended before the end of the second year of life.

The vaccine vial should be shaken to homogenize the suspension. The vaccine should be injected intramuscularly. The anterolateral aspect of the upper thigh is the preferred site of injection, or into the deltoid muscles of older children. 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. It is recommended that in patients with thrombocytopenia or bleeding disorders the vaccine be administered subcutaneously. Do not inject by the intravascular route. A sterile syringe and sterile needle should be used for each injection.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients. Hypersensitivity after previous administration of diphtheria, tetanus or pertussis vaccines.

The administration of DTP should be postponed in subjects suffering from acute severe febrile illness.

DTP is contra-indicated if the child has experienced an encephalopathy of unknown aetiology occurring within 7 days following previous vaccination with pertussis containing vaccine. In these circumstances the vaccination course should be continued with DT.

4.4 Special warnings and precautions for use

Vaccination should be preceded by a review of the medical history (especially with regard to previous vaccination and possible occurrence of undesirable events) and a clinical examination.

If any of the following events occur in temporal relation to receipt of DTP, the decision to give subsequent doses of vaccine containing the pertussis component should be carefully considered.

Temperature of 40°C within 48 hours, not due to another identifiable cause.
Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours.
Persistent crying lasting ≥3 hours occurring within 48 hours.
Convulsions with or without fever occurring within 3 days.

There may be circumstances such as a high incidence of pertussis, when the potential benefits outweigh possible risks.

A history of febrile convulsions, a family history of convulsions, a family history of SIDS (Sudden Infant Death Syndrome) and a family history of an adverse event following DTP vaccination do not constitute contraindications.

HIV infection is not considered as a contraindication for diphtheria, tetanus and pertussis vaccination. The expected immunological response may not be obtained after vaccination of immunosuppressed patients e.g. patients on immunosuppressive therapy.

As with all injectable vaccines, appropriate medical treatment should always be readily available in case of anaphylactic reactions following the administration of the vaccine. For this reason, the vaccinee should remain under medical supervision for 30 minutes after vaccination.

DTP should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. DTP should under no circumstances be administered intravenously.

4.5 Interaction with other medicinal products and other forms of Interaction

There is no known contraindication to the simultaneous administration of this vaccine with other standard vaccines during the same vaccination session provided that a different syringe and needle and a separate injection site are used.

DTP (whole cell) can be given safely and effectively at the same time as BCG, *Haemophilus influenzae* type b, polio (OPV and IPV), Hepatitis B and vitamin A supplementation.

In patients receiving immunosuppressive therapy or patients with immunodeficiency, an adequate response may not be achieved.

In order to avoid possible interactions between several medicinal products, any other ongoing treatment should be systematically reported to your doctor.

4.6 Pregnancy and lactation

Not Applicable

4.7 Effects on ability to drive and use machines

Not Applicable

4.8 Undesirable effects

Mild local or systemic reactions are common. Pain, erythema (redness), induration and oedema (swelling) may occur within 48 hours at the injection point or persist for several days. The formation of a subcutaneous nodule, persisting for several weeks, may accompany these reactions. Fever above 38°C, unusual crying within 24 to 48 hours following vaccination may occur. Rare cases of aseptic abscesses have been reported.

Allergic symptoms: rash (skin eruption), urticaria and in exceptional cases, anaphylactic shock (allergic shock) or Quincke's oedema (variety of urticaria with sudden swelling of face and neck) rarely occur.

Very rarely, attacks of hypotonus-hyporeactivity, persistent crying syndrome, convulsions with or without fever and exceptionally, acute encephalopathy (neurological disease) following vaccination tends to be attributed to the pertussis component.

There is no scientific evidence that these reactions have any permanent consequences for the children.

4.9 Overdose

Not Applicable, as DTwP vaccine is to be administered as per the pediatric immunization schedule under the direct supervision of physicians.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Immunogenicity studies in infants given three doses of DTwP vaccine starting at 6 weeks of age have shown up to 100% infants developed a seroprotective antibody level (≥ 0.1 IU/ml) for diphtheria and tetanus antigen.

For whole-cell pertussis, no threshold protective response has been widely-accepted in the evaluation of the response to immunization. The magnitude of the response for each vaccine component is compared based on the responses in test and control groups for the assay IgG Bordetella pertussis antibody and anti-PT antibody titres were found comparable in DTwP and in comparator groups after completion of the primary vaccination.

5.2 Pharmacokinetic properties

Evaluation of Pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data

The Animal toxicology studies of the DTwP vaccine was carried out in Swiss albino mice, Dunken Hartley guinea pigs and New Zealand white rabbits in following three studies:

- Acute toxicity studies
- Single dose toxicity studies
- Local tolerance test in Rabbit

Conclusions: The data from the three studies was analyzed and following results were obtained:

- No pre-terminal death

- No toxic signs or tissue reaction at the site of injection
- No significant dose related effects on the body weight and organ weight

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- 2-phenoxyethanol
- Aluminium phosphate gel
- Sodium chloride (Physiological saline)

6.2 Incompatibilities

There is no known contraindication to the simultaneous administration of this vaccine with other standard vaccines during the same vaccination session, provided that a different syringe and needle and a separate injection site are used.

6.3 Shelf life

2 years from the date of manufacturing when stored between 2°C and 8°C.

6.4 Special precautions for storage

Store at a temperature between 2°C and 8°C, protect from light.
Once opened, multi-dose vials should be kept between 2°C and 8°C.
The vaccine must not be frozen.

6.5 Nature and contents of container

The vaccine is filled in Single dose (0.5 ml), Two doses (1.0ml), Five doses (2.5ml) and Ten doses (5,0 ml) presentations in USP Type 1 glass vial and stoppered with rubber stopper and sealed with flip off aluminium seal.

6.6 Special precautions for disposal

The disposal shall be done as per the standard hospital procedures.

SUMMARY OF PRODUCT CHARACTERISTICS

7. MARKETING AUTHORISATION PREQUALIFICATION HOLDER

Panacea Biotec Ltd.
Malpur, Baddi, Distt Solan,
Himachal Pradesh – 173205, India
Tel. : 01795-674036
E-mail : corporate@panaceabiotec.com
Website: https://www.panaceabiotec.com

8. MARKETING AUTHORISATION NUMBER(S)

License No: MB/07/632

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

The details of the manufacturing authorization certificates obtained from Licensing Authority, India for DTwP vaccine manufactured at Vaccine Formulation Plant (VFP), Baddi, Himachal Pradesh, India are as mentioned below:

- Date of first authorization: October 27, 2010
- Renewal of the authorization: granted on September 29, 2012 valid up to 28.09.2017
- Renewal of the authorization: granted on September 29, 2017 valid up to 28.09.2022
- Retained upto September 28, 2027