120x200 mm

For the use of a Registered Medical Practitioner or Hospital or Laboratory only

Panacea Biotec
Innovation in support of life

DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE (ADSORBED) IP

DESCRIPTION

Diphtheria, tetanus and inactivated whole cell pertussis (Adsorbed) IP is a uniform suspension of diphtheria toxoid, tetanus toxoid and pooled bulk of whole cell pertussis. These antigens are finally adsorbed on aluminium phosphate gel and suspended in physiological saline solution to which 2-Phenoxyethanol is added as a preservative.

The product has an appearance of a white or almost white material which sediments at the bottom of the container defining two phases: a clear supernatant is essentially protein-free composed of physiological saline with the preservative substance dissolved, plus a aluminium phosphate gel with the antigen adsorbed on it. When shaken, a white or almost white suspension is formed, lasting for some minutes, which is the form in which the product is to be administered.

COMPOSITION

Each dose 0.5 ml contains:

DiphtheriaToxoid	20 Lf (30 IU)
TetanusToxoid	7.5 Lf
(60 IU in mice and 40 IU in guinea pigs)	
Inactivated w- *B. Pertussis*	12 OU (4 IU)
2-phenoxyethnol	2.5 mg
Aluminium content	0.25 mg
Physiological saline	q. s.

DOSAGE FORM

DTP Vaccine is a sterile suspension for intramuscular injection.

INDICATION

DTP is indicated for active immunization against diphtheria, tetanus and pertussis in infants from 6 weeks onwards.

DOSE AND METHOD OF ADMINISTRATION

Preparation for 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.

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.

USE IN SPECIAL POPULATIONS

As DTP is not intended for use in adults, information on the safety of the vaccine when used during pregnancy or lactation is not available.

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.

If there is any doubt, it is essential to consult your doctor.

WARNINGS AND PRECAUTIONS

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 40.0°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 contra-indications.

HIV infection is not considered as a contra-indication 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.

INTERACTIONS

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.

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. Rare cases of aseptic abscesses have been reported.

Fever above 38°C, unusual crying within 24 to 48 hours following vaccination.

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).

Very rarely, attacks of hypotonus-hyporeactivity, persistent crying syndrome, convulsions with or without fever.

Exceptionally, acute encephalopathy (neurological disease).

Neurological disorders following vaccination tend to be attributed to the pertussis component.

Oedematous reactions of the lower limbs. These reactions are sometimes accompanied by fever, pain and crying.

To report an adverse experience related to DTP of Panacea Biotec Limited, please contact us at the following details:
E-mail id:pvg@panaceabiotec.com, Fax no.:+91-11-41679069, Mobile no.:+91-9650138282.

OVERDOSE

No data on overdose has been reported.

PHARMACOLOGICAL PROPERTIES

DTP contains diphtheria (D), tetanus (T) toxoids and Inactivated whole cell Pertussis bacteria (wP), adsorbed on aluminium phosphate as adjuvant.

The diphtheria and tetanus toxoids are prepared from the toxins of cultures of *Corynebacterium diphtheriae* and *Clostridium tetani* respectively by formalin inactivation using established technology. The wP component is obtained by heat inactivation of phase I culture of *Bordetella pertussis* bacteria.

The primary vaccination schedule consists of three doses within the first six months of life at intervals of at least 4 weeks.

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.

SHELF-LIFE

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

PRESENTATION

Single dose vial containing 0.5 ml of vaccine.
Two doses vial containing 1.0 ml of vaccine.
Five doses vial containing 2.5 ml of vaccine.
Ten doses vial containing 5.0 ml of vaccine.

STORAGE AND HANDLING INSTRUCTIONS

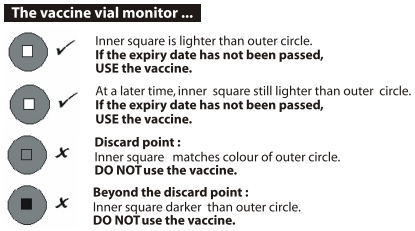
Store at a temperature between 2°C and 8°C, protect from light.

Once opened Multi-dose vials should be kept between 2°C and 8°C. Multi-dose vials of DTP from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 4 weeks, provided that all of the following conditions are met (as described in the *WHO policy statement: The use of opened multi dose vials in subsequent immunization sessions. WHO/V&B/00.09)*:

- The expiry date has not passed;
- The vaccines are stored under appropriate cold chain conditions;
- The vaccine vial septum has not been submerged in water;
- Aseptic technique has been used to withdraw all doses;
- The vaccine vial monitor (VVM) has not reached the discard point.

THE VACCINE MUST NOT BE FROZEN

Figure of the Vaccine Vial Monitor (VVM)



Vaccine Vial Monitors (VVMs) supplied by TEMPTIME Corporation, U.S.A are put on all DTP vaccine vials. The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is simple. "Focus on the central square". If the colour of this square is lighter than the colour of the circle, the vaccine can be used. If the colour of the central square is same as that of the circle or of darker than the circle, the vaccine vial should be discarded.

Manufactured by :
Panacea Biotec Ltd.
Malpur, Baddi, Tehsil Nalagarh,
Distt. Solan (H.P.) - 173 205, India.

PMPIS021