**PACKAGE INSERT**

**DTP Vaccine**
**(ADSORBED DIPHTHERIA TETANUS PERTUSSIS VACCINE)**
**Reg. No. : MAL20041068A**

**DESCRIPTION :**
A sterile, whitish turbid liquid, free from evident clumps after shaking.
This vaccine contains Purified Diphtheria and Tetanus Toxoids and Inactivated Whooping cough organisms. 1ml of this vaccine contains the toxoids which are adsorbed onto 3mg of Aluminium Phosphate. (Aluminium content per dose of 0.5ml is 0.33mg). Thimerosal 0.1mg/ml (0.01% w/v) is used as a preservative.
The potency of the Vaccine per single human dose (0.5ml) is at least 30 IU for Diphtheria, 4 IU for Pertussis and for Tetanus 60 IU (determined in mice) or 40 IU (determined in guinea pig).
**COMPOSITION:**
**1 Dose : 0.5ml**
One ml contains :-

| | |
|---|---|
| Purified Diphtheria Toxoid ..... | 40 Lf |
| Purified Tetanus Toxoid ..... | 15 Lf |
| Inactivated B. Pertussis | 24 OU |
| Aluminium phosphate (Adjuvant) ..... | 3 mg (0.33mg as Al. per dose of 0.5ml) |
| Thimerosal (Preservative) ..... | 0.1mg (0.01% w/v) |

**ACTION AND MODE OF MECHANISMS OF ACTION :**
Adsorbed Diphtheria-Tetanus-Pertussis Vaccine stimulates active immunity of human body to promote the development of antibodies against Diphtheria, Tetanus and Pertussis.
**PHARMACOLOGY (SUMMARY OF PHARMACODYNAMICS AND PHARMACOKINETICS) :**
Not applicable.
**TOXICOLOGY (Brief ) :**
Irreversibility and Specific Toxicity Tests were conducted on guinea pigs.
The results showed no sign of Diphtheria, Tetanus and Pertussis intoxication due to lethal toxins.
**INDICATIONS :**
For the prevention of Diphtheria, Tetanus and Pertussis in infants and young children.
**CONTRAINDICATION :**
There are few contraindications to the first dose of DTP. Fits of abnormal cerebral signs in the newborn period or other serious neurological abnormality are contraindications to the Pertussis component. DT should be given instead. A second or subsequent dose of DTP should not be given to a child who has suffered a severe reaction to the previous dose. The Pertussis component should be omitted, and only DT given for the remainder of the course. Pertussis containing vaccines are contraindicated in children with a personal or family history of central nervous system disease.
**SIDE EFFECTS / ADVERSE REACTIONS :**
Slight temporary swelling, tenderness and redness at the site of the 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. Very rare neurological complications, allegedly due to the Pertussis component have been observed but are rare in comparison to those observed in the course of the disease.

**PRECAUTIONS / WARNINGS :**
* Shake well before use
* Vaccine is injected intramuscularly.
* Do not administer intravenously
* It should be given with caution to persons with a history or family history of allergic reactions and those with a history or a family history of convulsion.
* Should not be administered to those with febrile illness.
* A solution of 1 in 1,000 adrenaline should be readily available for immediate injection in case of anaphylactic reaction

**DRUG INTERACTION** : Not reported.
**PREGNANCY AND LACTATION** : Not applicable.
**RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION**
The vaccine vial should be **shaken well vigorously** to homogenize the suspension before use. The 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. A sterile needle and sterile syringe should be used for each injection.

**Primary vaccination :**
One dose of 0.5ml injection at 3, 4 and 5 months of age.
**Booster dose** : 18 months to 2 years old.
In countries where pertussis is of particular danger to young infants,***
DTP immunization should be started as soon as possible with the first dose given as early as 6 weeks, and two subsequent doses given at 4 weeks intervals.
**' As Vaccination Schemes vary from country to country, the advised schedule for each country must be in accordance with the National Recommendation. '**
DTP Vaccine can be given safely and effectively at the same time as BCG, Measles, and Polio vaccines (OPV and IPV), Hepatitis B, Haemophilus influenzae type b, Yellow Fever vaccine and Vitamin A supplement. WHO recommends that, where resources permit, an additional dose of DTP be given approximately one year after completion of the primary doses. However, the need for additional booster doses of DTP, DT or Td should be addressed by individual national immunization programmes.
**IMMUNE DEFICIENCY**
Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with DTP vaccine according to standard schedules.
**INFORMATION ON USAGE OF MULTI-DOSE VIALS**
Once opened, multi-dose vials should be kept between +2°C and +8°C and must not be frozen. **Multi-dose vials from which one or more doses of vaccine have been withdrawn during an immunization session may be used in subsequent immunization session 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 session. WHO/V&B/00.09):
* The vaccine has been opened...
* The vaccine is 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), if attached, has not reached the discard point. (see figure).

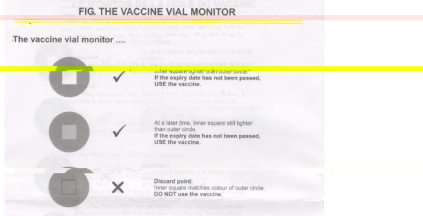
**SYMPTOMS AND TREATMENT FOR OVERDOSAGE, AND ANTIDOTE(S)**
Not documented.

**PACKING / PACK SIZES :**
The vaccine comes in vials of 10 doses (5ml) and every 10 vials is packed within an inner box which is enclosed with a package insert.

**STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS :**
Stored at 2 to 8 °C. Do not freeze. Protect from light. The label of each vial is incorporated with a Vaccine Vial Monitor (VVM).

**Shelf Life :** 2 years

**FIG. THE VACCINE VIAL MONITOR**




Vaccine Vial Monitors (VVMs) are part of the label on DTP vaccines supplied through Life Lines. 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. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour as than the ring, then the vial should be discarded.

PT. KIMIA FARMA *
Jalan Pasteur no. 28 . Bandung 40161 . Indonesia
PO Box 1186 . Tel. +62 22 7035756, Fax. +62 22 2041306