FRONT

BIO FARMA DTP VACCINE

(ADSORBED DIPHTHERIA TETANUS PERTUSSIS VACCINE) **Reg. No.:MAL20041068AZ**

DESCRIPTION
A sterile, whitish turbid liquid, free from evident clumps after shaking. 1 mL of this vaccine contains Purified Diphtheria and Tetanus Toxoids which are adsorbed onto 3mg/mL Aluminium phosphate. (Aluminium content per dose of 0.5 mL is 0.33 mg). Thimerosal 0.1mg/mL (0.01 %w/v) is used as a preservative. The potency of the vaccine components per single human dose 0.5 mL 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 is 0.5 mL
One mL contains:
Purified diphtheria toxoid (Active Ingredient).....40 Lf
Purified tetanus toxoid (Active Ingredient)..... 15 Lf
Inactivated B. Pertussis (Active Ingredient).....24 OU
Aluminum phosphate as (Adjuvant)..... 3 mg
Thimerosal.....0.1 mg

PHARMACODYNAMICS
Adsorbed Diphtheria Tetanus Pertussis Vaccine stimulates active immunity of human body to promote the development of antibodies against Diphtheria Tetanus and Pertussis.

INDICATIONS:
For the prevention of Diphtheria Tetanus and Pertussis in infants and young children.

RECOMMENDED DOSE
Primary vaccination:
One dose of 0.5ml injection at 3, 4 and 5 months of age.
Booster : at 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, Haemophilius 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.

ROUTE OF ADMINISTRATION
The vaccine should be injected intramuscularly. The anterolateral aspect of the upper thigh is the preferred site of the injection. (An injection in to 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.

CONTRAINDICATIONS
DTP vaccine should not be given to individuals who had an anaphylactic reaction to a previous dose or to any constituent of the vaccine.

WARNINGS AND PRECAUTIONS
- 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 adrenalines should be readily available for immediate injection in case of anaphylactic reaction

INTERACTIONS WITH OTHER MEDICAMENTS
No interaction studies have been performed.

PREGNANCY AND LACTATION
No related study has been performed.

SIDE 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. Hypotonic hyporesponsive episodes have been reported. Febrile convulsions have been reported at a rate of one per 12500 doses administered. Administration of acetaminophen 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 DTwP and chronic nervous system dysfunction in children. Thus, there is no scientific evidence that hypotonic-hyporesponsive episodes and febrile convulsions have any permanent consequences for the children.

BACK

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SYMPTOMS AND TREATMENT OF OVERDOSE
Not reported and no related study has been performed.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE
Not applicable to the indicated population.

PRECLINICAL SAFETY DATA
No related study has been performed.

INSTRUCTIONS FOR USE
The vaccine vial should be shaken well to homogenize the suspension before use. The vaccine should be injected intramuscularly. A sterile syringe and a sterile needle should be used for each injection.

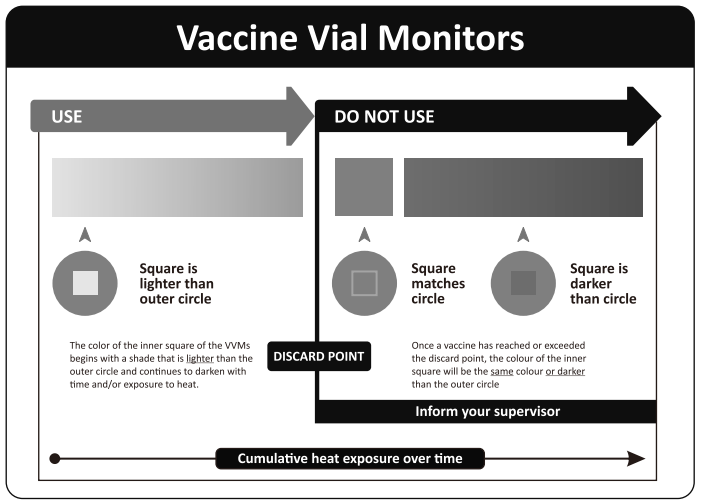
INFORMATION ON USAGE OF MULTI DOSE VIAL:
Multi-dose vials of DTP from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization session for up to a maximum 4 weeks, provided that all of following conditions are met (as described in the *WHO policy statement: Multi-dose Vial Policy (MDVP)WHO/IVB/14.07)*:
- The vaccine is currently prequalified by WHO;
- The vaccine is approved for use up to 28 days after opening the vial, as determined by WHO;
- The expiry date has not passed;
- The vaccine vial has been, and will continue to be, stored at WHO or manufacturer recommended temperatures; furthermore, the vaccine vial monitor (VVM), 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.

STORAGE CONDITION
Adsorbed DTP vaccine should be stored and transported between +2°C and +8°C. Do not freeze and protect from light.

SHELF LIFE
2 years when stored at temperature of +2 ~ +8 °C. The expiry date is shown on the label.

ATC CODE
J07AJ51

PRESENTATION
The vaccine comes in vials of 10 doses.



Vaccine Vial Monitors (VVMs) supplied by TempTime are part of the label on DTP vaccine. 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 squareis the same colour as the outer circle or of a darker colour as than the outer circle, then the vial should be discarded.

bioFarma

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Final folding dimension	:	100 x 35 mm	
Folding	:	3x fold	
Color	:	2 Color	PMS Black U PMS Yellow U
Manufactured	:	PT Bio Farma (Persero)	
Address	:	Jl. Pasteur No 28 Bandung 40161	
Product	:	DTP Vaccine 10 Doses (Malaysia)	
Material	:	HVS 70 gsm	
Dimension	:	100 x 280 mm, ± 2 mm	
Scale	:	100 %	
Edition	:	010624-DTP-MAL	
Note	:		

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