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## BIO FARMA ADSORBED DT VACCINE
*(ADSORBED DIPHTHERIA TETANUS VACCINE)* **Reg. No.:MAL20041069AZ**

**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 and at least 40 IU for Tetanus Toxoid.

**COMPOSITION:**
1 dose is 0.5 mL
One mL contains:
Purified diphtheria toxoid (Active Ingredient).....40 Lf
Purified tetanus toxoid (Active Ingredient)..... 15 Lf
Aluminum phosphate as (Adjuvant)..... 3 mg
Thimerosal.....0.1 mg

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

**INDICATIONS:**
For the prevention of Diphtheria and Tetanus in children.

**RECOMMENDED DOSE**
**Primary vaccination:**
One 0.5 ml injection at 3, 4 and 5 months of age followed by a booster at 18 months to 2 years of age.
Booster: One 0.5 ml injection below 7 years of age. **'As Vaccination Schemes vary from country to country, the advised schedule for each country must be in accordance with the National Recommendation.'**
Adsorbed DT Vaccine may be given safely and effectively at the same time as BCG, Measles, Rubella, Mumps, Polio Vaccines (OPV and IPV), Hepatitis B, Hib, Yellow Fever and Vitamin A Supplement. **IMMUNE DEFICIENCY** Individuals infected with human immunodeficiency virus (HIV), whether asymptomatic or symptomatic, should be immunized with DT vaccine according to standard schedules.

**ROUTE OF ADMINISTRATION**
Adsorbed DT vaccine is generally injected intramuscularly. The preferred site of injection is the upper arm.

**CONTRAINDICATIONS**
A second or subsequent dose of DT should not be given to a child who has suffered a severe reaction to the previous dose.

**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**
Slight temporary swelling, tenderness and redness at the site of the injection and occasional fever.

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

**EFFECTS ON ABILITY TO DRIVE AND USE MACHINE**
There is no evidence that adsorbed DT vaccine effects on ability to drive and use machines.

**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. Adsorbed DT vaccine is recommended for children below 7 years of age when contraindications to pertussis component of DTP vaccine exist. For individuals 7 years and older, a special adsorbed vaccine for adults, Td is recommended.

**INFORMATION ON USAGE OF MULTI DOSE VIAL:**
Multi-dose vials of DT 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

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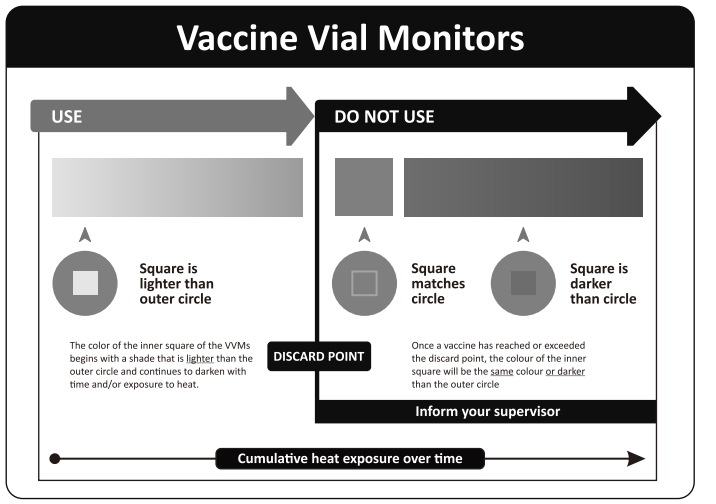
recommended temperatures; furthermore, the vaccine vial monitor (VVM), if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

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

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

**ATC CODE**
J07AM51

**PRESENTATION**
The vaccine comes in vials of 10 doses.




Vaccine Vial Monitors (VVMs) supplied by TempTime are part of the label on DT 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.

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Jl. Pasteur No. 28 Bandung 40161-Indonesia
PO Box 1136, Tel. +62 22 2033755, Fax. +62 22 2041306

Product Registration Holder/Importer/Distributor:
Propharm (M) Sdn. Bhd.
No.8, Jalan Udang Harimau 2
Medan Niaga Kepong
51200 Kuala Lumpur, Malaysia
Tel.: 03-62436389
Fax.: 03-62436385
e-mail:propharm2000@hotmail.com
Edition: 010324-DT-MAL
Revision Date: 01.03.2024

GTIN:08994957004964

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|---|---|---|---|---|---|---|---|
| Manufactured | : | PT Bio Farma (Persero) | Material | : | HVS 70 gsm | Final folding dimension | : 100 x 35 mm |
| Address | : | Jl. Pasteur No 28 Bandung 40161 | Dimension | : | 100 x 280 mm, ± 2 mm | Folding | : 3x fold |
| Product | : | DT Vaccine 10 Doses (Malaysia) | Scale | : | 100 % | Color | : 2 Color |
| | | | Edition | : | 010324-DT-MAL | PMS Black U<br>PMS Lime 376U | |
| | | | Note | : | | | |

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