PACKAGE INSERT

Adsorbed DT Vaccine
(ADSORBED DIPHTHERIA TETANUS VACCINE)
Reg. No.: MAL20041069A

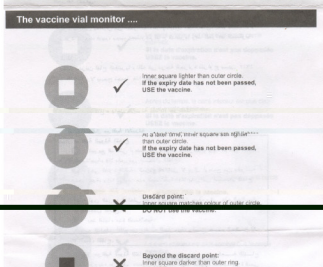
DESCRIPTION :
A sterile, whitish turbid liquid, free from evident clumps after shaking.
1ml of this vaccine contains Purified Diphtheria and Tetanus Toxoids which are adsorbed onto 3mg/ml Aluminium Phosphate (Aluminium Content per dose of 0.5ml is 0.33mg). Thimerosal 0.1mg/ml (0.01%w/v) is used as a preservative. The potency of the vaccine components per single human dose 0.5ml is at least 30 IU (International Units) for Diphtheria Toxoid and at least 40 IU for Tetanus Toxoid.
COMPOSITION :
1 dose is 0.5ml
One ml contains :-
Purified Diphtheria Toxoid (Active Ingredient)... 40 Lf
Purified Tetanus Toxoid (Active Ingredient)..... 15 Lf
Aluminium phosphate (Adjuvant) ..... 3 mg
Thimerosal (Preservative) ..... 0.1 mg
ACTION AND MODE OF MECHANISMS OF ADMINISTRATION
Adsorbed Diphtheria Tetanus Vaccine stimulates active immunity of human body to promote the development of antibodies against Diphtheria and Tetanus.
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 and Tetanus intoxication due to lethal toxins.
INDICATIONS :
For the prevention of Diphtheria and Tetanus in children.
CONTRAINDICATION :
A second or subsequent dose of DT should not be given to a child who has suffered a severe reaction to the previous dose.
SIDE EFFECTS / ADVERSE REACTIONS :
Slight temporary swelling, tenderness and redness at the site of the injection and occasional fever.
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 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.
Primary vaccination :
One 0.5ml injection at 3, 4 and 5 months of age followed by a booster at 18 months to 2 years of age.
Booster : One 0.5ml injection below 7 years of age.
' As Vaccination Schemes vary from country to country, the above-mentioned 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 vaccines and Vitamin A supplement.
IMMUNOSUPPRESSED :
Individuals infected with human immunodeficiency virus (HIV), whether asymptomatic or symptomatic, may not develop adequate immunity to diphtheria and tetanus toxoids 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 expiry date has not passed;
- 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 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 attached 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 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 square is the same colour as the ring or of a darker colour than the ring, then the vial should be discarded.

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