طبقا للـ WHO website و الموافقة تسرى على الـ Vial of 10doses.

English

Adsorbed Td Vaccine

DESCRIPTION
The vaccine contains purified tetanus and diphtheria toxoids, with a reduced dose of the diphtheria component. One dose of 0.5 ml has a potency of less than 30 IU of diphtheria toxoid, and not less than 40 IU of tetanus toxoids. The toxoids are adsorbed onto 3 mg/ml aluminum phosphate. Thimerosal 0.1 mg/ml is used as a preservative. The vaccine is used for the active immunization of adults and children 7 years of age and older against diphtheria and tetanus.

COMPOSITION	Dose	
Volume	0.5	ml
Purified Diphtheria toxoid	2	Lf
Purified Tetanus toxoid	7.5	Lf
Aluminum phosphate	1.5	mg
Thimerosal	0.05	mg

ADMINISTRATION
The vaccine vial should be shaken to homogenize the suspension. The vaccine should be injected intramuscularly in the upper arm. A sterile needle and sterile syringe should be used for each injection.

IMMUNIZATION SCHEDULE
A single 0.5 ml dose of the vaccine is recommended. The use of Td vaccine to replace other Diphtheria and Tetanus-containing vaccines should be in accordance with official recommendation due to the low dose of diphtheria toxoid in this vaccine. The use of vaccine for primary immunization and in pregnancy has not been evaluated. It may be given at the same time as measles, polio (OPV and IPV), hepatitis B, yellow fever vaccines and vitamin A supplementation.

Note :
The ACIP (Advisory Committee on Immunization Practices) has published recommendation for use of Tetanus and Diphtheria Toxoids Adsorbed, for adult use in pregnant women. Td vaccine may be used as a primary immunization for persons contraindicated for DTP Vaccine, from 7 years of age. According to ACIP (Advisory Committee on Immunization Practices), they should receive two doses of 0.5 ml of adsorbed Td with reduced dose of diphtheria for adults at an interval of at least four-eight weeks. A third dose is recommended at least 6 months after the second dose.

According to WHO insert model, " Td vaccine may be used as a primary immunization for persons from 7 years of age. They should receive two doses of 0.5 ml of adsorbed Td with reduced dose of diphtheria for adults at an interval of at least four weeks. A third dose is recommended at least 6 months after the second dose. After aprimary immunization course of either DTP or Td, adsorbed Td for adults may be used as a booster at intervals of approxiamately 10 years, but with a minimum of at least one year between doses. It can be safely replace monovalent tetanus toxoid (TT) vaccine, including during pregnancy."

SIDE EFFECTS
Some transitional tenderness and redness at the site of the injection and occasional fever may occur.
It is safe to give during pregnancy.

CONTRAINDICATIONS
A second or subsequent dose of Td should not be given to an individual who suffers a severe reaction to the previous dose.

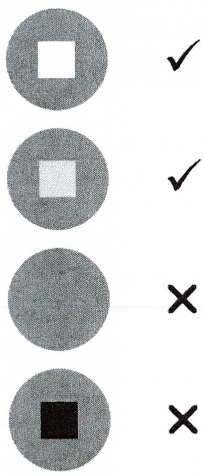
Immune deficiency
Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with Td vaccine according to standard schedules.

STORAGE
Td vaccine should be protected from light and stored and transported between +2°C and +8°C.
IT MUST NOT BE FROZEN.
Once opened, multi-dose vials should be kept between +2°C and +8°C.
Multi-dose vials of Td 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 of 4 weeks, provided that all of the 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 of the vaccine has not passed;
- The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer- recommended temperaturs; 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.

PRESENTATION
The vaccine comes in vials of 1 and 10 dose.

FIG. THE VACCINE VIAL MONITOR



Inner square lighter than outer circle.
If the expiry date has not been passed,
USE the vaccine.

At a later time, inner square still lighter than outer circle.
If the expiry date has not been passed,
USE the vaccine.

Discard point:
Inner square matches colour of outer circle.
DO NOT use the vaccine.

Beyond the discard point:
Inner square darker than outer circle
DO NOT use the vaccine.

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