طبقاً لـ WHO website وهذه النشرة تسري على العبوة 1 dose ampoule
10 dose vial
ولا تسري على باقي العبوات

DIPHTHERIA AND TETANUS VACCINE ADSORBED FOR ADULTS AND ADOLESCENTS

DESCRIPTION

Diphtheria and tetanus vaccine adsorbed for adults and adolescents (Td) is prepared by combining purified diphtheria toxoid and purified tetanus toxoid. The antigens are adsorbed onto Aluminium Phosphate as adjuvant. Thiomersal is added as preservative. The vaccine has the appearance of a greyish - white suspension and does not contain any horse serum protein. Therefore, it does not induce sensitization to sera of equine origin. The vaccine meets the requirements of W.H.O. and B.P. when tested by the methods outlined in W.H.O., TRS. 980 (2014) and B.P.

POTENCY

Each single 0.5 ml human dose contains
Diphtheria Toxoid $\leqslant$ 5 Lf ($\geqslant$ 2 IU)
Tetanus Toxoid $\geqslant$ 5 Lf ($\geqslant$ 40 IU)
Adsorbed on Aluminium Phosphate, $Al^{+++} \leqslant 1.25$ mg
Preservative : 0.005% Thiomersal

هيئة الدواء المصرية
الإدارة المركزية للمستحضرات الحيوية والمبتكرة
والدراسات الاكلينيكية
إدارة تسجيل المستحضرات الحيوية
نشرة معتمدة
تاريخ ١٣ / ٤ / ٢٠٢١

INDICATIONS

For primary vaccination and revaccination of adults and adolescents, who are having contraindications of DTP.
Primary vaccination and revaccination of children older than 7 years. In order to prevent allergic reactions to the protein of Diphtheria toxoid, the quantity of the toxoid has been markedly reduced.
After a primary immunisation course of either DTP or Td, adsorbed Td for adults may be used as a booster at intervals of approximately 10 years, but with a minimum of at least one year between doses. It can safely replace monovalent tetanus toxoid (TT) vaccine, including during pregnancy.
The vaccine can be safely and effectively given simultaneously with BCG, Measles, Polio Vaccine (IPV and OPV), Hepatitis B, Yellow fever Vaccine, *Haemophilus influenzae* type b, Varicella vaccine and vitamin A supplementation.

APPLICATION AND DOSAGE

Two injections of 0.5 ml at least four weeks apart followed by a third injection 6 to 12 months after the second dose. The vaccine should also be given as a booster immunisation every 5 to 10 years.

METHOD OF INNOCULATION

The vaccine should be injected intramuscularly. The preferred site for injection is deltoid muscles. Care should be taken not to inject into the blood vessel or the skin. Only sterile syringes and needles should be used for each injection. The vaccine should be well shaken before use.
Once opened, multi-dose vials should be kept between +2°C and +8°C. Multi-dose vials of Diphtheria and tetanus vaccine adsorbed for adults and adolescents vaccine from which one or more doses of vaccine have been removed during an immunisation session may be used in subsequent immunisation sessions for upto a maximum of 28 days, provided that all of the following conditions are met (as described in the WHO policy statement: Handling of multi dose vaccine vials after opening, WHO/IVB/14.07):

- The vaccine is currently prequalified by WHO;
- The vaccine is approved for use for 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 temperatures; furthermore, the vaccine vial monitor, 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.

The vaccine should be visually inspected for any foreign particulate matter and / or variation of physical aspect prior to administration. In event of either being observed, discard the vaccine.

REACTIONS

Reactions are generally mild and confined to the site of injection. Some inflammation may occur together with transient fever, malaise and irritability. Occasionally a nodule may develop at the site of injection but this is rare.

PRECAUTIONS

ADRENALINE INJECTION (1:1000) MUST BE IMMEDIATELY AVAILABLE SHOULD AN ACUTE ANAPHYLACTIC REACTION OCCUR DUE TO ANY COMPONENT OF THE VACCINE. For treatment of severe anaphylaxis the initial dose of adrenaline is 0.1-0.5 mg (0.1-0.5 ml of 1:1000 injection) given S/C or I/M. Single dose sholud not exceed 1 mg (1 ml). For infants and children the recommended dose of adrenaline is 0.01 mg/kg (0.01 ml/kg of 1:1000 injection). Single paediatric dose should not exceed 0.5 mg (0.5 ml). The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be lifesaving. It

should be used at the first suspicion of anaphylaxis.
As with the use of all vaccines the vaccinee should remain under observation for not less than 30 minutes for possibility of occurrence of immediate or early allergic reactions. Hydrocortisone and antihistaminics should also be available in addition to supportive measures such as oxygen inhalation.
Special care should be taken to ensure that the injection does not enter a blood vessel.
IT IS EXTREMELY IMPORTANT WHEN THE PARENT, GUARDIAN, OR ADULT PATIENT RETURNS FOR THE NEXT DOSE IN THE SERIES, THE PARENT, GUARDIAN, OR ADULT PATIENT SHOULD BE QUESTIONED CONCERNING OCCURRENCE OF ANY SYMPTOMS AND/OR SIGNS OF AN ADVERSE REACTION AFTER THE PREVIOUS DOSE.

DRUG INTERACTIONS
If Td and TIG or Diphtheria Antitoxin are administered concurrently, separate syringes and separate sites should be used.
As with other intramuscular injections, use with caution in patients on anticoagulant therapy.
Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids used in greater than physiologic doses), may reduce the immune response to vaccines.

CONTRAINDICATIONS AND WARNINGS
The vaccine should not be given to persons who showed a severe reaction to a previous dose of Diphtheria and Tetanus vaccine.
A history of systemic allergic or neurologic reactions following a previous dose of Td is an absolute contraindication for further use.
Immunization should be deferred during the course of an acute illness. Vaccination of persons with severe, febrile illness should generally be deferred until these persons have recovered. However, the presence of minor illnesses such as mild upper respiratory infections with or without fever should not preclude vaccination.

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

STORAGE OF THE VACCINE
The vaccine should be stored in a dry, dark place at a temperature between 2-8°C. Transportation should also be at 2- 8°C. DO NOT FREEZE.

SHELF LIFE
36 months from date of manufacture.

PRESENTATION
1 dose ampoule of 0.5 ml
10 dose vial of 5 ml
20 dose vial of 10 ml

THE VACCINE VIAL MONITOR (Optional)

- ✓ Inner square lighter than outer circle.
  If the expiry date has not passed, USE the vaccine.
- ✓ At a later time, inner square still lighter than outer circle.
  If the expiry date has not 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 ring.
  DO NOT use the vaccine.

Vaccine Vial Monitors (VVMs) are part of the label on Diphtheria and Tetanus Vaccine Adsorbed for Adults and Adolescents supplied through Serum Institute of India Pvt. Ltd. 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.

Manufactured by:
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Protection from birth onwards
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