Ministry of Health
Central Administration for
Pharmaceutical Affairs
General Directorate of Registration
Pharmacology Committee

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وزارة الصحة
الإدارة المركزية للشئون الصيدلية
الإدارة العامة للتسجيل
لجنة الفارماكولوجي

Serial: 000070/ 2011
خطابات

السيدة الدكتورة / رئيس قسم تسجيل المستحضرات الحيوية

تحية طيبة وبعد .....

بخصوص النشرة الخاصة بمستحضر :

Trade Name: DT pediatric.
Each 0.5ml contains:
Diphtheria toxoid ≤ 25LF(≥30IU)
Tetanus toxoid ≥ 5LF(≥40IU)
Pharmaceutical form: vial
Manufacturer: Serum Institute of India

نتشرف بأن نحيط سيادتكم علماً بأنه قد تم تحديث النشرة الخاصة بالمستحضر السابق و إعتمادها بعد التحديث بتاريخ ٢٠١١/٢/١٧ من قبل لجنة الفارماكولوجى

و مرفق لسيادتكم صورة من النشرة الداخلية المعتمدة

و تفضلوا بقبول وافر الإحترام....

مقرر لجنة الفارماكولوجى
د.أمل محمد عبدالله
٢٠١١/٢/٢٨

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DIPHTHERIA AND TETANUS VACCINE ADSORBED (Pediatric)

DESCRIPTION

Diphtheria and Tetanus Vaccine Adsorbed (DT) is prepared by combining purifie diphtheria toxoid and purified tetanus toxoid. The antigens are adsorbed onto aluminiu phosphate as adjuvant. Thiomersal is added as preservative. The vaccine has th 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 th requirements of WHO, EP and IP when tested by the methods outlined in WHO, TRS (1990), 800, EP and IP

POTENCY

Each single 0.5 ml human dose contains
Diphtheria Toxoid ≤ 25 Lf (≥ 30 IU)
Tetanus Toxoid ≥ 5 Lf (≥ 40 IU)
Adsorbed on Aluminium Phosphate, Al^{+++} ≤ 1.25 mg
Preservative : 0.01% Thiomersal

INDICATIONS

The vaccine is recommended for use in childhood immunization instead of DTP vaccine when contraindications to the pertussis component exist. The DT vaccine is recommended for children below 8 years of age; for persons 8 years and older, a special dT vaccine, containing a reduced amount of diphtheria toxoid is recommended. The vaccine can be safely and effectively given simultaneously with BCG, Measles, Polio vaccines (IPV and OPV), Hepatitis B, Yellow fever vaccine, Haemophilus influenzae-B and Varicella vaccine.

APPLICATION AND DOSAGE

Three injections of 0.5 ml at least four weeks apart followed by a fourth dose 6 to 12 months later.

METHOD OF INOCULATION

The vaccine should be injected intramuscularly. The preferred site for injection in infants and young children is the anterolateral aspect of the upper thigh or the deltoid muscle in older children.
Only sterile needles and syringes 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 DT 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 4 weeks, provided that all of the following conditions are met

- The expiry date has not passed.
- The vaccines are 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).

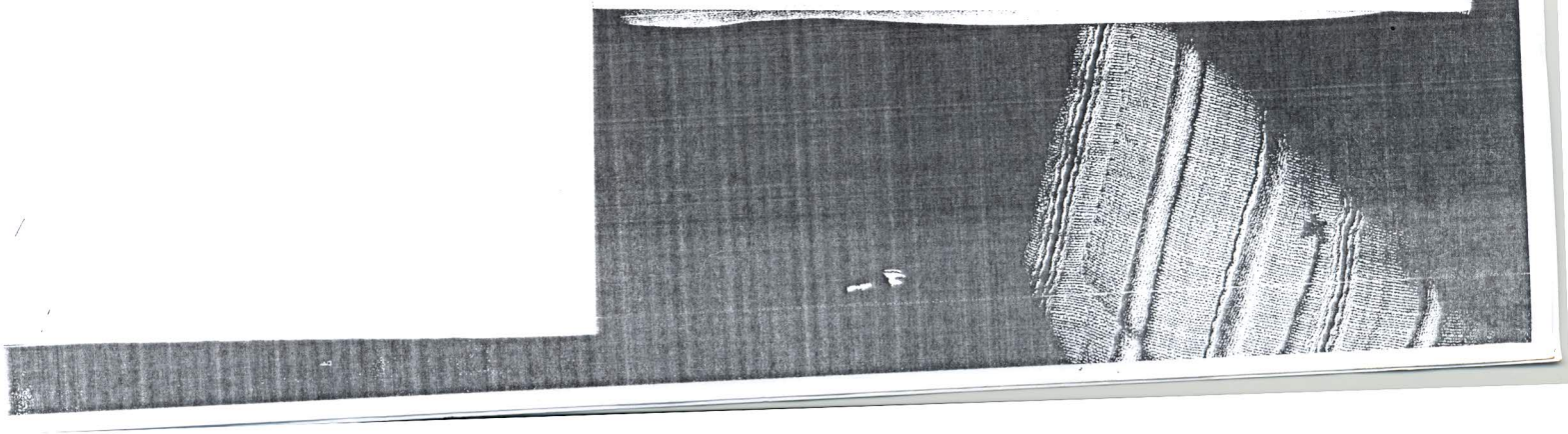
The vaccine should be visually inspected for any foreign particulate matter and / or variation of physical aspect prior to administration. In event of either being observed, discard the vaccine.

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. In older children the local and general reactions may be more severe due to sensitivity to the diphtheria protein.

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 (0.1-0.5ml of 1:1000 injection) given s/c or i/m. Single dose should not exceed 1 mg (1ml). For infants and children the recommended dose of adrenaline is 0.01mg/kg (0.01ml/kg of 1:1000 injection). Single pediatric dose should not exceed 0.5mg (0.5ml). 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.



Efcorlin hydrochloride 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 DT 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 tetanus toxoid vaccine
A history of systemic allergic or neurologic reactions following a previous dose of DT 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.

HIV INFECTION

DT vaccine may be used in children with known or suspected HIV infection. Although the data are limited and further studies are being encouraged. There is no evidence to date of any increased rate of adverse reactions using this vaccine in symptomatic or asymptomatic HIV infected children

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

Thirty six 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 supplied through Serum Institute of India 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:
SERUM INSTITUTE OF INDIA LTD.
212/2, Hadapsar, Pune 411028, INDIA

Protection from birth onwards

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