English

DTP VACCINE

طبقاً للـ WHO website.
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٢٠٢١/٣/١

DESCRIPTION

The vaccine contains purified diphtheria and tetanus toxoids and inactivated whooping cough organisms. The toxoids are adsorbed onto 3 mg/ml aluminum phosphate. Thimerosal 0.1 mg/ml is used as a preservative The potency of the vaccine per single human dose is at least 4 IU for pertussis, 30 IU for diphtheria and for tetanus 60 IU (determined in mice) or 40 IU (determined in guinea pig).

COMPOSITION	Paediatric Dose
Volume	0.5 ml
Purified Diphtheria toxoid	20 Lf
Purified Tetanus toxoid	7.5 Lf
Inactivated Pertussis bacterial	12 OU
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 or deep subcutaneously. The anterolateral aspect of the upper thigh is the preferred site of injection. (An injection into a child's buttocks may cause injury to the sciatic nerve and is not recommended). It must not be injected into the skin as this may give rise to local reaction. One dose is 0.5 ml. A sterile needle and sterile syringe should be used for each injection.

IMMUNIZATION SCHEDULE

In countries where pertussis is of particular danger to young infants, DTP immunization should be started as soon as possible with the first dose given as early as 6 weeks, and two subsequent doses given at 4-week intervals.
DTP vaccine can be given safely and effectively at the same time as BCG, measles and polio vaccines (OPV and IPV), hepatitis B, *Haemophilus influenzae* b, Yellow Fever vaccine and vitamin A supplementation. WHO recommends that, where resources permit, an additional dose of DTP be given approximately one year after completion of the primary doses. However, the need for additional booster doses of DTP, DT or Td should be addressed by individual national immunization programmes. DTP vaccine can be given safely at the same time as other vaccines according to national immunization schedules.

SIDE EFFECTS

Mild local or systemic reactions are common. Some temporary swelling, tenderness and redness at the site of injection together with fever occur in a large proportion of cases. Occasionally severe reactions of high fever, irritability and screaming develop within 24 hours of administration. Hypotonic-hyporesponsive episodes have been reported. Febrile convulsions have been reported at a rate of one per 12500 doses administered. Administration of acetaminophen at the time of and 4-8 hours after immunization decreases the subsequent incidence of febrile reactions. The national childhood encephalopathy study in the United Kingdom showed a small increased risk of acute encephalopathy (primarily seizures) following DTP immunization. However subsequent detailed reviews of all available studies by a number of groups, including the United States Institute of Medicine, the Advisory Committee on Immunization Practices, and the paediatric associations of Australia, Canada, the United Kingdom and the United States, concluded that the data did not demonstrate a causal relationship between DTwP and chronic nervous system dysfunction in children. Thus there is no scientific evidence that hypotonic-hyporesponsive episode and febrile convulsions have any permanent consequences for the children.

CONTRAINDICATIONS

DTP vaccine should not be given to individuals who had an anaphylactic reaction to a previous dose or to any constituent of the vaccine.

Immune deficiency

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

STORAGE

DTP vaccine should be 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 DTP 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 following conditions are met (as described in the *WHO policy statement : The use of opened multi-dose vials in subsequent immunization sessions. WHO/ V&B/ 00.09*) :

- 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 dose;
- The vaccine vial monitor (VVM), if attached, has not reached the discard point. (see figure)

PRESENTATION

The vaccine comes in vials of 10 doses.

هيئة الدواء المصرية
الإدارة المركزية للمستحضرات الحيوية والمتكررة
إدارة تسجيل المستحضرات الحيوية
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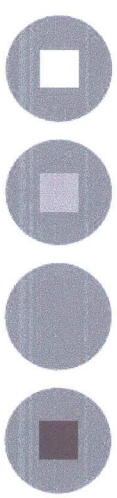
٢٠٢١/٣/١

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 DTP 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 outer circle or of a darker colour as than the outer circle, then the vial should be discarded.

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