English

Pentabio DTP-HB-Hib Vaccine

DESCRIPTION

The vaccine is a homogeneous liquid containing purified diphtheria and tetanus toxoids, inactivated whooping cough (pertussis) organisms, highly purified, non-infectious particles of hepatitis B surface antigen (HBsAg) and Hib component as a bacterial subunit vaccine containing highly purified, non-infectious Haemophilus influenzae type b (Hib) capsular polysaccharide chemically conjugated to a protein of tetanus toxoid. The HBsAg is produced by DNA recombinant technology in yeast (Hansenulla polymorpha) cells . The vaccine is adsorbed on to 3 mg/mL aluminum phosphate. Thimerosal 0.05 mg/mL is used as a preservative. The polysaccharide is derived from Hib bacteria grown in chemically defined media, and subsequently purified through a series of ultrafiltration steps. The potency of the vaccine per single human dose is at least 4 IU for pertussis, 30 IU for diphtheria, 60 IU for tetanus (determined in mice), 10 mcg HBsAg and 10 mcg Hib.

COMPOSITION	Paediatric Dose
Volume	0.5 mL
Diphtheria toxoid	20 Lf (≥ 30 IU)
Tetanus toxoid	5 Lf (≥ 60 IU)
Inactivated B. Pertussis	12 OU (≥ 4 IU)
HBsAg	10 mcg
Hib (PRP -TT)	10 mcg
Al^{3+} as aluminum phosphate	0.33 mg
Thimerosal	0.025 mg

ADMINISTRATION

The liquid vaccine vial should be shaken before use to homogenize the suspension. The vaccine should be injected intramuscularly. 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 paediatric dose is 0.5ml. A sterile syringe and sterile needle must be used for each injection.

IMMUNIZATION SCHEDULE

The vaccine should NOT be used for the birth dose.

In countries where pertussis is of particular danger to young infants, the combination vaccine 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.
The DTP-HB-Hib vaccine can be given safelyand effectively at the same time as BCG, measles, polio (OPV or IPV), and yellow fever vaccines and vitamin A supplementation. If DTP-HB-Hib vaccine is given at the same time as other vaccines, it should be administered at a separate site. It should not be mixed in the vial or syringe with any other vaccine unless it is licensed for use as a combined product.

SIDE EFFECTS

The type and rate of severe adverse reactions do not differ significantly from the DTP, HB and Hib vaccine reactions described separately.
For DTP, 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 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 DTP and chronic nervous system dysfunction in children. Thus there is no scientific evidence that these reactions have any permanent consequences for the children*

Hepatitis B vaccine is very well tolerated. In placebo-controlled studies, with the exception of local pain, reported events such as myalgia and transient fever have not been more frequent than in the placebo group. Reports of severe anaphylactic reactions are very rare. Available data do not indicate a causal association between hepatitis B vaccine and GuillainBarré syndrome, or demyelinating disorders including multiple sclerosis, nor is there any epidemiological data to support a causal association between hepatitis B vaccination and chronic fatigue syndrome, arthritis, autoimmune disorders, asthma, sudden infant death syndrome, or diabetes.
Hib vaccine is very well tolerated. Localized reactions may occur within 24 hours of vaccination, when recipients may experience pain and tenderness at the injection site. These reactions are generally mild and transient. In most cases, they spontaneously resolve within two to three days and further medical attention is not required. Mild systemic reactions, including fever, rarely occur following administration of Hib vaccines. More serious reactions are very rare; a causal relationship between more serious reactions and the vaccine has not been established.
*In Weekly Epidemiological Record, No. 18, 7 May 1999. Page 139

CONTRAINDICATIONS

Known hypersensitivity to any component of the vaccine, or a severe reaction to a previous dose of the combination vaccine or any of its constituents is an absolute contraindication to subsequent doses of the combination vaccine or the specific vaccine know to have provoked an adverse reaction. There are few contraindications to the first dose of DTwP - fits or abnormal cerebral signs in the newborn period or other serious neurological abnormality are contraindications to the pertussis component. In this case, the vaccines should not be given as a combination vaccine but DT should be given instead of DTwP and Hep B and Hib vaccines given separately. The vaccine will not harm individuals currently or previously infected with the hepatitis B virus.

Immune deficiency

Individuals infected with the human immuno-deficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with combined vaccine according to standard schedules.

STORAGE

The components of the combination vaccine must be stored and transported between +2° C and +8°C.
The DTP-HB-Hib vaccine MUST NOT BE FROZEN.

Multi-dose vials of vaccine 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 0.5 mL (1 dose), 2.5 mL (5 dose) and 5 mL (10 dose).

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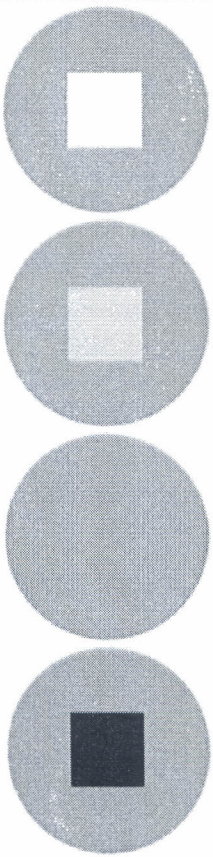
FIG. THE VACCINE VIAL MONITOR



✓ 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-HB-Hib** 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 circle, 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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