Eupenta™ Inj.

Adsorbed Diphtheria-Tetanus-whole cell Pertussis-Hepatitis B(rDNA) and *Haemophilus influenzae* type b conjugate vaccine

DESCRIPTION

Eupenta™ Inj. 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 Tetanus toxoid. The HBsAg is produced by DNA recombinant technology in yeast (*Saccharomyces Cerevisiae*) cells. The vaccine adsorbed on aluminum hydroxide. Aluminum hydroxide is used as an adjuvant and preserved with thimerosal. 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, 15 Lf for diphtheria, 10 Lf for tetanus and 10 ㎍ for HBsAg.

COMPOSITION

	Pediatric Dose
Volume	0.5 mL
Diphtheria toxoid	15 Lf
Tetanus toxoid	10 Lf
Pertussis antigen	≥ 4 IU
Hepatitis B surface antigen	10 ㎍
Haemophilus influenzae type b - Tetanus Toxoid conjugate	30 ~ 50 ㎍
Aluminum hydroxide	0.39 mg
Thimerosal	0.01 w/v%

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

Eupenta™ Inj. 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 Eupenta™ Inj. can be given safely and effectively at the same times as BCG, measles, polio(OPV or IPV), and yellow fever vaccines and vitamin A supplementation. If Eupenta™ Inj. 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 DTwP, HepB and Hib vaccine reactions described separately.

For DTwP, 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 DTwP and chronic nervous system dysfunction in children. Thus there is no scientific evidence that these reactions have any permanent consequences for the children.(In Weekly Epidemiological Record, No. 18, 7 May 1999. Page 139)

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 Guillain-Barré 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.

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 known 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 vaccine 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.

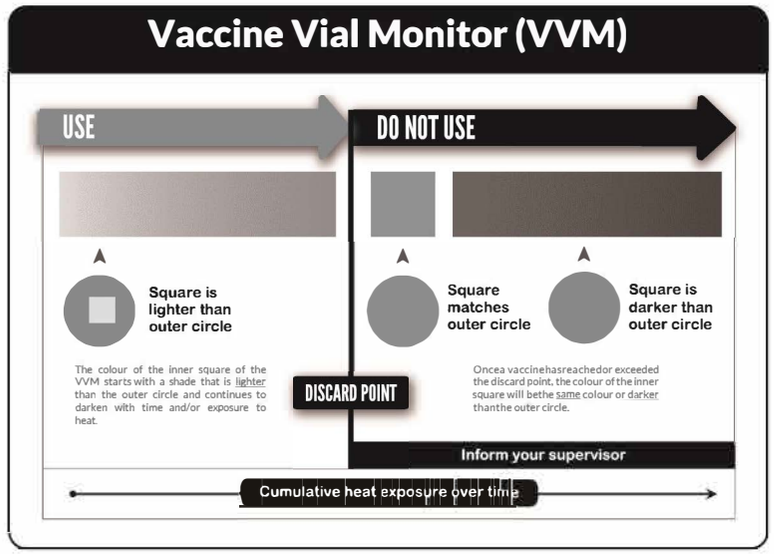
STORAGE

The components of the combination vaccine must be stored and transported between +2℃ and +8℃. **The Eupenta™ Inj. MUST NOT BE FROZEN.**

All opened WHO-prequalified multi-dose vials of vaccines should be discarded at the end of the immunization session, or within six hours of opening, whichever comes first, UNLESS the vaccine meets all four of the criteria listed below. If the vaccine meets the four criteria, the opened vial can be kept and used for up to 28 days after opening. The criteria are as follows (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 (see figure).

Fig. The Vaccine Vial Monitor



PRESENTATION

The vaccine comes in single dose vials or vials of 10 doses.

HOW SUPPLIED

Single dose: 0.5mL/vial x 10 vials
Multi-doses: 5.0mL/vial x 10 vials

MANUFACTURED BY

LG Chem
151, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea
[Source of Hep B, Hib bulk material] LG Chem
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[Source of D.T.P. bulk material] BB-NCIPD Ltd.
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※ Issue date: 11 Jan. 17
※ Revision date: 28 Mar. 24

LG Chem