

## **SUMMARY OF PRODUCT CHARACTERISTICS**

**1. Trade name of the drug product (finished product)**

Eupenta™ Injection (Adsorbed Diphtheria-Tetanus-Pertussis-Hepatitis B(rDNA) and *Haemophilus influenzae* type b conjugate vaccine)

**2. Qualitative and quantitative composition**

Each 0.5 mL of Eupenta™ Inj. contains 15 Lf of diphtheria toxoid, 10 Lf of tetanus toxoid, more than 4 IU of inactivated pertussis suspension, 10 µg of purified hepatitis B surface antigen (HBsAg) and 10 µg of PRP as active ingredients.

**3. Pharmaceutical form**

Slightly opaque white suspension for injection

**4. Clinical particulars**

4.1 Therapeutic Indications

For active primary immunization against diphtheria, tetanus, pertussis, hepatitis B and *Haemophilus influenzae* type b disease in infants from 6 weeks of age.

4.2 Dosage and Administration

Eupenta™ is for intramuscular use only.

Recommended for administration of 3 doses (1 dose = 0.5 mL) at 6, 10, 14 weeks of age by intramuscular injection.

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 pediatric dose is 0.5 mL. A sterile syringe and sterile needle must be used for each injection.

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#### 4.3 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 HepB 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 immune-deficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with combined vaccine according to standard schedules.

#### 4.4 Special warnings and special precautions for use

Eupenta™ Inj. should be administered in the gluteal region, and it must not be administered intravenously.

Thimerosal (an organomercuric compound) has been used in the manufacturing process of this medicinal product and residues of it are present in the final product. Therefore, sensitization reactions may occur.

As with any injectable vaccine, appropriate medical supervision and treatment should always be readily available in case of immediate allergic reactions, such as anaphylactic shock or anaphylactic reaction, following administration of the vaccine. Before administering the vaccine, precautions should be taken to avoid undesirable reactions.

These precautions include: review of the individual's medical history, particularly regarding hypersensitivity reactions to previous administration of any type of vaccine, as well as the individual's history of recent health disorders and any previous vaccinations.

The administration of any subsequent dose of a vaccine containing the whole-cell pertussis component should be carefully considered if, in connection with the administration of DTP vaccine, one or more of the following effects have been observed:

- 40.0° C temperature within 48 hours following vaccination (not due to other identifiable causes);
- collapse or shock (hypotonic hyporesponsive episodes) within 48 hours following vaccination;

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- persistent crying lasting more than 3 hours during the 48 hours following vaccination;
- convulsions, with or without fever, within 3 days following vaccination.

There may be circumstances, such as high incidence of pertussis, when potential benefits outweigh possible risks.

HIV seropositivity does not represent a contraindication to vaccination. Patients with an immunodeficiency disorder or receiving immunosuppressive therapy may have a reduced immunological response. Individuals infected with the human immuno-deficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with combined vaccine according to standard schedules.

The vaccine must not be injected into a blood vessel.

Eupenta™ inj. (DTwP-HepB-Hib fully liquid combined vaccine) should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. A fine needle should be used for the vaccination and firm pressure applied to the site (without rubbing) for at least two minutes following administration.

#### 4.5 Interaction with other medicaments and other forms of interaction

Not applicable.

#### 4.6 Pregnancy and lactation

Not applicable. This vaccine is intended only for paediatric use.

#### 4.7 Undesirable effects

The type and rate of adverse reactions of the DTwP-HepB-Hib fully liquid combination vaccine 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

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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-Barre 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.

#### **Data from clinical studies:**

##### **Cardiac disorders**

Cardio-respiratory arrest

##### **Eye disorders**

Dacryostenosis acquired, Eye discharge

##### **Gastrointestinal disorders**

Abdominal pain, Constipation, Diarrhoea, Infantile colic, Mouth ulceration, Stomatitis, Vomiting

##### **General disorders and administration site conditions**

Decreased activity, Injection site reaction, Pyrexia, Injection site erythema, Injection Site Swelling, Injection Site Induration, Injection site rash (Injection Site Skin Flare)

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### **Hepatobiliary disorders**

Neonatal cholestasis

### **Immune system disorders**

Hypersensitivity

### **Infections and infestations**

Acarodermatitis, Amoebiasis, Atypical pneumonia, Bacterial sepsis, Body tinea, Bronchiolitis, Bronchitis, Carbuncle, Conjunctivitis bacterial, Exanthema subitum, External ear cellulitis, Folliculitis, Fungal skin infection, Furuncle, Gastroenteritis, Impetigo, Meningitis bacterial, Nail infection, Nasopharyngitis, Omphalitis, Oral candidiasis, Otitis externa, Otitis media, Otitis media acute, Pneumonia, Pneumonia bacterial, Pneumonia viral, Rhinitis, Sepsis, Septic shock, Skin bacterial infection, Tinea versicolour, Upper respiratory tract infection, Urinary tract infection, Varicella, Viral infection, Viral rash, Viral rhinitis, Wound infection

### **Injury, poisoning and procedural complications**

Arthropod bite, Chest injury, Post procedural contusion, Post procedural contusion, Thermal burn

### **Metabolism and nutrition disorders**

Loss of appetite

### **Musculoskeletal and connective tissue disorders**

Myalgia, Neoplasms benign, Malignant and unspecified (Incl cysts and polyps), Haemangioma

### **Nervous system disorders**

Generalised tonic-clonic seizure, Sleepiness

### **Psychiatric disorders**

Irritability, Restlessness

### **Reproductive system and breast disorders**

Testicular swelling

### **Respiratory, thoracic and mediastinal disorders**

Allergic pharyngitis, Aspiration, Bronchial hyperreactivity, Cough, Nasal congestion, Rhinitis allergic,

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Sneezing, Upper-airway cough syndrome

**Skin and subcutaneous tissue disorders**

Dermatitis allergic, Dermatitis atopic, Dermatitis contact, Dermatitis diaper, Generalised erythema, Miliaria, Rash, Rash vesicular, Seborrhoeic dermatitis

**5. Pharmacological properties**

5.1 Pharmacodynamic properties

Not applicable

5.2 Pharmacokinetic properties

Not applicable

**6. Pharmaceutical particulars**

6.1 List of excipient(s)

Adjuvant	: Aluminum Hydroxide Gel (as aluminum)-----	0.39 mg
Buffering agent	: Sodium phosphate, heptahydrate-----	0.08 mg
	: Sodium phosphate, dihydrate-----	0.733 mg
Tonicity agent	: Sodium Chloride -----	4.25 mg
Stabilizer	: Polysorbate 80 -----	5 µg
Preservative	: Thimerosal -----	0.01w/v%
Diluent	: Water for injection-----	q.s.

6.2 Incompatibilities : None known

6.3 Shelf-life : 36 months

6.4 Special precautions for storage

Eupenta™ is stable for 36 months at 2-8°C. It can be used safely for 36 months when stored at 2-8°C

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[36-46°F] in a refrigerator. It should not be frozen.

#### 6.5 Nature and contents of container

Elastomeric closures and glass container (vial) for Injections

The containers are colorless and transparent, and have no bubbles.

Packs contain ;

- 0.5 mL × 10 vials
- 5.0 mL × 10 vials

#### 6.6 Instruction for use/handling

It should be well shaken before use.

And it must be administered by intramuscular injection.

### 7. Marketing authorization holder

LG Chem, Ltd.

### 8. Marketing authorization number

5115

### 9. Date of first authorization / renewal of authorization

Number and date of first authorization : 5115 / May 27, 2014

Number and date of renewal : NA

### 10. Date of (partial) revision of the text

March 14, 2017