Quinvaxem inj. (DTP-HeBp-Hib fully liquid combined vaccine)

1. NAME OF THE MEDICINAL PRODUCT

Quinvaxem inj. (DTP-HeBp-Hib fully liquid combined vaccine) is a combination of purified Diphtheria toxoid for toxoid of Corynebacterium diphtheriae, tetanus toxoid for toxoid of Clostridium tetani, killed whole cells of Bordetella pertussis andacellular pertussis toxoid, hepatitis B (HeBp) and Haemophilus influenzae type b (Hib) conjugated vaccine.

2. QUALITIES AND QUANTITATIVE COMPOSITION

Quinvaxem inj. contains:
- Purified Diphtheria toxoid
- Tetanus toxoid
- Killed whole cells of Bordetella pertussis
- Acellular pertussis toxoid
- Hepatitis B (HeBp)
- Haemophilus influenzae type b (Hib) conjugated vaccine

3. PREPARATION AND PURIFICATION

The vaccine is prepared by aqueous dispersion of diphtheria toxoid, tetanus toxoid, Bordetella pertussis (whole cells and acellular), hepatitis B (HeBp) and Haemophilus influenzae type b (Hib) conjugated vaccine. Purified diphtheria toxoid is obtained from Corynebacterium diphtheriae ATCC 10403 and Clostridium tetani ATCC 11334. The killed whole cells of Bordetella pertussis and acellular pertussis toxoid are obtained from cultures of B. pertussis and Bordetella pertussis. The hepatitis B (HeBp) vaccine contains hepatitis B surface antigen (HBsAg). Haemophilus influenzae type b conjugated vaccine contains the capsular polysaccharide of Hib, purified capsular polysaccharide, cross-reacting material (Cross Reacting Material, CRM 197) (cross-reacting behaving) in formaldehyde inactivated and purified. Purine Diphtheria toxoid contains aluminium phosphate as adjuvant.

4. PHARMACOLOGICAL PROPERTIES

4.1 Therapeutic indications

Quinvaxem inj. (DTP-HepB-Hib fully liquid combined vaccine) is indicated for infants regardless of whether or not they have received hepatitis B vaccine at birth. Active primary and booster immunisation of infants and toddlers for protection against diphtheria, tetanus, pertussis, hepatitis B, and invasive illness caused by Haemophilus influenzae type b (Hib) conjugated vaccine, in children 3–60 months of age, is presented by the following schedule: 0, 1, 6 months or 0.5, 1, 1.5 years; at least one month apart, starting at any age of 6 weeks.

4.2 Method of administration

The vaccine is administered by subcutaneous injection in the anterolateral thigh or alternatively in the deltoid region in children 13–24 months of age. Intramuscular administration may lead to an immune response that is falsely considered to be protective. The vaccine must not be mixed with other medicinal products.

4.3 Contraindications

The vaccine is contraindicated in children with known severe allergic reaction to any vaccine component or to children having shown signs of hypersensitivity to any vaccine ingredient or in children having shown signs of hypersensitivity after previous administration of diphtheria, tetanus, pertussis, hepatitis B, or Haemophilus influenzae type b (Hib) conjugated vaccine. Also contraindicated is the use of the vaccine in children born to HIV-infected mothers, whose mother tested positive for HBsAg. Quinvaxem inj. (DTP-HepB-Hib fully liquid combined vaccine) should not be administered to children with known severe thrombocytopenia or bleeding disorders since bleeding after intramuscular injection may occur in these individuals. Quinvaxem inj. (DTP-HepB-Hib fully liquid combined vaccine) must not be mixed with other vaccines in the same syringe.

4.4 Special precautions for use

In immunocompromised individuals, impaired immunity after HIV infection or with other immune deficiencies in which vaccine-induced immunity diminishes, the immune response may be reduced. The vaccine is not recommended in children with certain systemic disorders or conditions of immune deficiency such as AIDS. Quinvaxem inj. (DTP-HepB-Hib fully liquid combined vaccine) must not be mixed with other vaccines in the same syringe.

4.5 Interaction with other medicinal products and other forms of interaction

Quinvaxem inj. (DTP-HepB-Hib fully liquid combined vaccine) is to be administered intramuscularly or subcutaneously with other injections or medication that are administered to the same site of injection or in any temporal relationship with other paediatric vaccines if this fits conveniently in the immunisation schedule. The vaccines should be administered at separate sites or in any temporal relationship with other vaccines if this fits conveniently in the immunisation schedule.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of action

The active ingredients of the vaccine have been shown to stimulate the immune system. The immune system produces antibodies against the vaccine components, which are useful in protecting the body from infection. The antibodies are produced by B cells, which are a type of white blood cell.

5.2 Pharmacokinetic properties

Not applicable.

6. PHARMACOLOGICAL PARTICULARS

6.1 List of excipients

Not applicable.

6.2 Incompatibilities

Not applicable.

6.3 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product

Not applicable.

7. CLINICAL PHARMACOLOGY

7.1 Clinical trials

Clinical trials are studies in which vaccines are given to humans to assess their safety and efficacy. The results of clinical trials are used to determine whether a vaccine is effective and safe for use in the general population.

7.2 Clinical studies

Clinical studies are experiments conducted in humans to determine the safety and efficacy of a vaccine. These studies are conducted in phases, with each phase focusing on a different aspect of the vaccine's effectiveness.

7.3 Post-marketing surveillance

Post-marketing surveillance is a system for monitoring the safety and effectiveness of a vaccine after it has been approved and marketed. This system helps identify any unexpected side effects or adverse events.

8. MARKETING AUTHORISATION Holder

See section 4.7 for details on the marketing authorisation holder.

9. DATES OF FIRST AUTHENTICATION AND REVISING OF THE AUTHENTICATION

See section 4.7 for details on the dates of first authentication and revising of the marketing authorisation.

10. DATES OF REVISION OF THE TEXT

See section 4.7 for details on the dates of revision of the text.