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QUINVAXEM

Novartis Vaccines & Diagnostics

Abbreviated product characteristics for Quinvaxem inj.

(DTP-HepB-Hib fully liquid combined vaccine), suspension for injection. Diphtheria, tetanus, pertussis, hepatitis B recombinant and *Haemophilus influenzae* type b (Hib) combined vaccine.

Composition

Quinvaxem inj. is a ready-to-use, fully liquid combined vaccine. The diphtheria and tetanus toxoids are obtained from *Corynebacterium diphtheriae* and *Clostridium tetani* cultures, respectively, by formaldehyde inactivation and purification. The pertussis suspension component is obtained from *Bordetella pertussis* cultures after inactivation and purification. The hepatitis B surface antigen (HBsAg) is produced in genetically engineered yeast cells *(Hansenula polymorpha)* carrying the relevant gene for the HBsAg. The antigen is purified and inactivated by several physicochemical steps. The *H. influenzae* type b component is made of purified capsular oligosaccharides conjugated to CRM_{197} (Cross Reacting Material), a non-toxic mutant of diphtheria toxin, prepared from *C. diphtheriae* cultures.

One 0.5 ml dose contains ≥ 30 IU purified diphtheria toxoid, ≥ 60 IU purified tetanus toxoid, ≥ 4 IU inactivated *B. pertussis* whole-cell suspension, 10 µg HBsAg, 10 µg Hib oligosaccharide conjugated to approximately 25 µg of CRM_{197} protein and aluminium phosphate (0.3 mg Al^{3+}) as adjuvant forming a whitish sediment.

Quinvaxem is free of preservatives. Thiomersal may be present in traces as a residue of the manufacturing process.

Pharmaceutical form

Suspension for intramuscular injection. After shaking, the product has a milky appearance.

Therapeutic indications

Active immunisation of infants and toddlers for protection against diphtheria, tetanus, pertussis, hepatitis B, and invasive illness caused by *H. influenzae* type b. Can be used interchangeably with other DTP-HepB-Hib vaccines.

Dosage

Applicable national vaccination recommendations and/or WHO guidelines are to be followed.

Primary vaccination of infants (first year of life): 3 doses of 0.5 ml each, at least one month apart, starting as early as 6 weeks of age. Can be given to children who have received hepatitis B vaccine at birth. Should not be used for hepatitis B vaccination at birth.

Reinforcing vaccination of toddlers (13–24 months after birth): one booster dose of 0.5 ml.

Method of administration

Intramuscular injection in the anterolateral thigh or alternatively in the deltoid region in children 13–24 months after birth. Simultaneous administration as a separate injection with other common childhood vaccines, according to locally recommended immunisation schedules is possible.

Contraindications

Should not be given to children: with known hypersensitivity to any vaccine component; having shown signs of hypersensitivity after previous administration of diphtheria, tetanus, pertussis, hepatitis B or Hib vaccines; who have experienced an encephalopathy of unknown aetiology after a previous vaccination with vaccine containing pertussis (in these cases vaccination should be continued with diphtheria, tetanus, hepatitis B and Hib vaccines).

As with other vaccines, vaccination should be postponed in children suffering from acute febrile illness (≥38°C).

Special warnings and precautions for use

Appropriate medical supervision and treatment should always be readily available in case of imme-

diate 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.

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
- 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 is not a contraindication. Patients with an immunodeficiency disorder or receiving immunosuppressive therapy may have a reduced immunological response.

Must not be injected into a blood vessel.

Should be administered with caution to subjects with thrombocytopaenia 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 2 minutes following administration.

Interaction with other medicinal products and other forms of interaction

Can be administered simultaneously with other vaccines (injectable or oral) at separate sites or in any temporal relationship with other paediatric vaccines, if this fits conveniently in the immunisation schedule.

Must not be mixed with other vaccines in the same syringe.

Immunological response may be reduced in patients undergoing immunosuppressive or corticosteroid treatment.

Undesirable effects

From clinical trials (1500 doses given to 512 healthy infants from 6 weeks of age), frequencies based on number of doses:

Very common (>1/10), Common (>1/100, ≤1/10), Uncommon (>1/1000, ≤1/100), Rare (>1/10 000, ≤1/1000), Very rare (≤1/10 000, including isolated reports).

- *Gastrointestinal disorders:* Common: diarrhoea, vomiting.
- *General disorders and administration site conditions:*Very common: injection site reactions (erythema, induration, pain). Common: fever. Rare: influenza-like illness.
- *Metabolism and nutrition disorders:* Common: feeding disorders.
- *Nervous system disorders:* Common: sleepiness.
- *Psychiatric disorders:* Very common: crying. Common: irritability. Uncommon: persistent crying.
- *Respiratory, thoracic and mediastinal disorders:* Rare: coughing.
- *Skin and subcutaneous tissue disorders:*

Uncommon: rash.

The systemic adverse reactions usually appeared within 48 hours after vaccination and in most cases disappeared spontaneously. All local and systemic reactions resolved without sequelae.

Allergic reactions, including anaphylactic reactions and urticaria, have been reported very rarely following vaccination with DTP, hepatitis B and Hib containing vaccines.

Adverse events should be reported to Berna Biotech Korea.

Storage
Store at a temperature between +2°C and +8°C. Do not freeze. Discard if vaccine has been frozen.

Special precautions
Shake well before use.

Marketing authorisation holder
Berna Biotech Korea Corporation
227-3 Gugal-dong, Giheung-gu
Yongin 449-903, Korea
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