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Haemophilus Influenzae Type b Conjugate Vaccine

Please read the package insert carefully and follow physician's guidance to use

[Drug Name]
Generic name: Haemophilus Influenzae Type b Conjugate Vaccine
English name: Haemophilus Influenzae Type b Conjugate Vaccine
Chinese Pinyin: b Xing Liuganshixueganjun Jiehe Yimiao

[Composition and Characteristic]
The vaccine is a preparation of purified capsular polysaccharide of Haemophilus influenzae type b that is covalently bound to tetanus toxoid and adsorbed with aluminum phosphate adjuvant. The final product is milky white suspension. It should not contain clumps that cannot disperse after shaking. This product contains no preservative.
Active ingredients: Haemophilus influenzae type b capsular polysaccharide
Excipients: aluminum phosphate, sodium chloride

[Eligibles]
Infants 2 months of age to children 5 years of age.

[Indications and Use]
The vaccine can induce humoral immune response in recipients following immunization. It is used to prevent invasive infections caused by Haemophilus influenzae type b including meningitis, pneumonia, septicemia, cellulitis, arthritis and epiglottitis.

[Strength]
0.5 ml per single prefilled syringe. Each single human dose is 0.5ml containing not less than 10μg of purified Haemophilus influenzae type b capsular polysaccharide.

[Administration and Dosage]
The vaccine should be injected subcutaneously at deltoid insertion area of the lateral upper arm. Vaccination of the anterolateral thighs(1/3 of the middle part) is recommended for infants under 12

months of age.
Infants at 2-6 months of age: Starting at 2 or 3 months of age, three doses (each dose is 0.5ml) shall be given at intervals of 1 or 2 months, and booster dose shall be given at 18 months of age.
Children at 6-12 months of age: Two doses (each dose is 0.5ml) shall be given at intervals of 1 or 2 months, and booster dose shall be given at 18 months of age.
Children at 1-5 years of age: only one dose (0.5ml) is required.

[Adverse Reactions]
Based on the clinical trial results obtained from 985 domestic subjects vaccinated with this vaccine, the possible adverse reactions are as following:
According to the incidence rate of adverse reactions recommended by Council of International Organizations of Medical Sciences (CIOMS), it is very common (≥10%), common (1%~10%, including 1%), uncommon (0.1%~1%, including 0.1%), rare (0.01%~0.1%, including 0.01%) and very rare (<0.01%).
Local adverse reactions:
Common: Erythema, swelling, induration, pain and itch.
Systemic adverse reactions:
Very common: Fever, crying and screaming
Common: fatigue, vomiting, anorexia, diarrhea, rash
Rare: headache
The above adverse reactions were mainly mild and moderate. Apart from fever, digestive tract symptom is comparatively obvious, most events happen within 24 hours after vaccination, which could be relieved spontaneously and disappeared within 24 hours. Treat according to the symptoms if necessary. In case of adverse reactions not mentioned above, please contact your doctor in time.

[Contraindications]
(1) Subjects with acute diseases, severe chronic diseases, chronic diseases at stage of acute attack or fever.
(2) Subjects with known allergic reactions to this vaccine or any other component of the vaccine, especially tetanus toxoid.
(3) Subjects with severe heart diseases, hypertension, hepatic or renal diseases.
(4) Subjects with encephalopathy, uncontrolled epilepsy, convulsions and other progressive nervous system diseases.

[Precautions]
(1) Use with caution in the following cases: family or individual with disease history of convulsion, chronic disease, epilepsy or allergies.
(2) Shake well before use. Do not use the vaccine if the container shows abnormalities, such as crack, foreign matters, clumps that cannot disperse after shaking, unclear label or expired.
(3) The optimum immune response of the vaccine may be affected in individuals receiving immunosuppressive therapy or immunosuppressed persons.
(4) Medications such as epinephrine should be available for first aid in case of severe allergic reactions. The recipients should be observed for at least 30 minutes after the injection.
(5) If the vaccine is administered with other vaccines at the same time, inject at different sites.

(6) In any case, the tetanus toxoid component in this vaccine cannot be used as a substitute for routine tetanus toxoid immunization
(7) Prohibit to freeze.
(8) The vaccine should not be injected intravenously and ensure that the injection does not enter the blood vessel.
(9) Once the vaccine is opened, it should be used immediately and used up in one go according to the prescribed dose.
(10) Keep the vaccine out of reach of children.

[Storage]
Store and transport at 2℃-8℃, protected from light.
Do not freeze.

[Packaging]
prefilled syringe,10μg / 0.5ml / syringe,1 syringe / box.

[Self Life]
24 months.

[Product Standard]
YBS00862021

[Product License Number]
GYZZ S20184001

[Marketing Authorization Holder and Address]
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