

WALVAX

Haemophilus Influenzae Type b Conjugate Vaccine

【Drug name】

Common name : Haemophilus Influenzae Type b Conjugate Vaccine
English name: Haemophilus Influenzae Type b Conjugate Vaccine
Bopomofu: b Xing Lluganshixueganjun Jiehe Yimiao

【Constituents and characters】

This vaccine is a preparation of Haemophilus influenzae type b capsular polysaccharide antigen covalently bound to tetanus toxoid protein. It is colorless and clear liquid.

Active ingredient: Haemophilus influenzae type b capsular polysaccharide

Auxiliary material: Sodium Chlorid

Composition : 1 dose (0.5ml) contains :

Haemophilus influenzae type b capsular polysaccharide.....10µg

Tetanus toxoid protein..... 20~34µg

Sodium Chloride3.75~4.75mg

【Eligibles】

Infants and children at the age of 2 months to 5 years.

【Function and use】

This vaccine can induce humoral immunity against Haemophilus influenzae Type b infections, including meningitis, pneumonia, septicemia, cellulitis, arthritis, epiglottitis etc.

【Specification】

0.5ml per vial for each single dose contains purified Haemophilus influenzae type b capsular polysaccharide not less than 10µg.

【Administration and dosage】

The vaccine should be administered intramuscularly in the 1/4 top of gluteal area or in the outer deltoid region of upper arm.

Administration and dosage:

An infant should receive 3 doses (0.5ml each), for 1 or 2 months intervals from age of 2 months, and a booster dose at 18 months of age.

An infant 6 to 12 months of age should receive 2 doses (0.5ml each) of vaccine at 1 or 2 months intervals and a booster dose at 18 months of age.

A child 1 to 5 years of age should receive one dose (0.5ml).

【Adverse reactions】

General slight reactions were observed after injection. The local reactions were mainly mild and usually resolved spontaneously, including pain, redness swelling, induration or pruritus at the injection site. Symptom can be treated when necessary.

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Systemic reactions like fever (mostly below 38.5 °C), occasional irritability, drowsiness, vomiting, diarrhea, loss of appetite, rare untypical rash, which could be spontaneous remission.

【Contraindications】

Do not use this vaccine in case of:

- (1) Subjects with acute disease, acute chronic disease, active stage of chronic disease and fever.
- (2) Subjects with known and established allergy to one of the ingredients of this vaccine especially the tetanus protein.
- (3) Subjects with acute heart disease, hypertension, brain disease, kidney and liver disease, active tuberculosis.

【Precautions】

- (1) Do not inject intravenously, intradermally, or subcutaneously and ensure the needle not to enter a blood vessel.
- (2) This vaccine should be carefully administered to subjects as following: subjects with family and individual have a convulsion history, chronic disease, history of seizures, anaphylaxis.
- (3) Shake fully before use. Do not use the vaccine if any not dispersed clot, flaw of vial, illegible label or after expiry date.
- (4) Immunosuppressive therapy or immunodeficiency patient may affect vaccine effectiveness.
- (5) Adrenaline should be available for acute allergic reactions occur. Subjects should be observed stay still at least 30mins after injection.
- (6) When allergic reaction happens, timely see the doctor at vaccination place or in hospital.
- (7) The vaccine should be administered at separate sites, concomitantly with one or more of vaccines.
- (8) At any case, the routine immunization of tetanus toxoid can not be replaced by the vaccine.
- (9) Administer immediately once product opens in accordance with human single dose for use.
- (10) Do not freeze.
- (11) Keep out of the reach of children.

【Storage】

Store and ship at 2 °C-8 °C, protected from light.

【Packaging】

Pack of 1ml Pre-filled syringe, 0.5ml/syringe/box

【Validity period】

The expiry date 24 months

【Standard for implementation】

WS-(S-002)-2011Z

【Product registration number】

GuoYaoZhunZi S20070010

【Manufacturer】

Enterprise: Yuxi Walvax Biotechnology Co., Ltd. **WALVAX**

Add: No. 83 South Dongfeng Road, High & New Technology Industries
Development Zone, Yuxi, Yunnan Province, China

Tel: 86-877-2076100 86-877-2076210 Fax: 86-877-2076918

Web site: www.walvax.com