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Group A and Group C Meningococcal Polysaccharide Vaccine

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

[Drug Name]
Generic Name: Group A and Group C Meningococcal Polysaccharide Vaccine
English Name: Group A and Group C Meningococcal Polysaccharide Vaccine
Chinese Pinyin: A Qun C Qun Naomoyanqiujun Duotang Yimiao

[Composition and Characteristic]
The vaccine is a preparation of purified capsular polysaccharide antigens extracted from the cultures of Neisseria meningitidis group A and C respectively and lyophilized after addition of an appropriate Lactose. The final product looks in a white loose powder shape, dissolving rapidly when added to sterilized water for injection. It shall turn into a clear liquid after reconstitution.
Active ingredients: Group A, and C Neisseria meningitides capsular polysaccharide
Excipients: lactose, sodium chloride
Diluent: nationally approved sterilized water for injection

[Eligibles]
Children over 2 years old and adults

[Indications and Use]
The vaccine can induce humoral immune response in recipients following immunization. It is used to prevent epidemic cerebrospinal meningitis caused by Neisseria meningitidis group A and C.

[Strength]
After reconstitution, it shall be 0.5ml per vial. Each single human dose is 0.5ml containing 50μg of group A and C polysaccharide respectively.

[Administration and Dosage]

(1) Reconstitute the vaccine with the sterilized water(0.5ml) according to the indicated amount. With gentle shaking the dried powder is easily dissolved. Use the reconstituted vaccine immediately.
(2) The vaccine should be injected subcutaneously at deltoid insertion area of the lower edge of the lateral upper arm
(3) 0.5ml per human dose for single use. The immunization shall be completed before meningococcal epidemic season.

[Adverse Reactions]
Common adverse reactions:
(1) Injection site pain and tenderness, mild and moderate reaction to local redness and swelling of injection site. Most of the reactions can be relived spontaneously within 2 to 3 days.
(2) A transient fever reaction may occur after vaccination. Most of them are mild fever reactions, which usually can be relived spontaneously after 1 to 2 days, and do not require treatment. For patients with moderate fever or fever for more than 48 hours, symptomatic treatment can be given.
Rare adverse reactions:
(3) Severe fever: symptomatic treatment should be given to prevent febrile seizures.
(4) Severe swelling of Injection site or other complications, corresponding treatment should be given.
Very rare adverse reactions:
(1) Allergic rash: usually a rash may occur within 72 hours after vaccination. It should be promptly treated and given anti-allergy treatment.
(2) Anaphylactic shock: usually occurs within 1 hour after vaccination. It should be promptly treated and given anti-allergy treatment.
(3) Allergic purpura: should be promptly treated when allergic purpura reaction occurs. Use corticosteroids to give anti-allergy treatment. Improper treatment or not timely may be complicated by purpuric nephritis.
(4) Angioneurotic edema and allergic neuritis are occasionally seen.
(5) Allergic exfoliative dermatitis is reported in the literature.
In addition to the above adverse reactions, induration and pruritus at the injection site, as well as fatigue, anorexia, headache, dizziness, vomiting, diarrhea, abdominal pain, drowsiness, irritability and other symptoms were also observed in the post marketing study of this product.

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

[Precautions]
(1) Use with caution in the following situations: family or individual with disease history of convulsion, chronic disease,epilepsy,allergies and lactating women
(2) The vaccine vial with cracks, unclear or invalid label, turbidity after re dissolution of the vaccine and other abnormal appearance shall not be used.
(3) Do not use the vaccine if the container shows any crack, unclear or invalid label or with abnormal appearance such as turbidity after reconstitution.

(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.

[Storage]
Store and transport at 2℃-8℃, protected from light.

[Packaging]
Vial,1 vial/box, 5 vial/box, vaccine diluent is nationally approved sterilized water for injection and packaged separately.

[Self Life]
24 months.

[Product Standard]
YBS00932021

[Product License Number]
GYZZ S20110015

[Marketing Authorization Holder and Address]
Beijing Zhifei Lvzhu Biopharmaccutical Co., Ltd
No.22, Tongjibei Road, Beijing Economic Technological Development Area, Beijing

[Manufacturer]
Name: Beijing Zhifei Lvzhu Biopharmaccutical Co., Ltd.
Address: No.22, Tongjibei Road, Beijing Economic Technological Development Area, Beijing
Post Code:100176
Telephone: 010-67870189
Fax:010-67870318
Website: www.vaccine.com.cn