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Meningococcal Group A and C Conjugate Vaccine

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

[Drug Name]

Generic Name: Meningococcal Group A and C Conjugate Vaccine

Trade Name: Mening A Con

English Name: Meningococcal Group A and C Conjugate Vaccine

Chinese Pinyin: A Qun C Qun Naomoyanqiujuun Duotang Jiehe Yimiao

[Composition and Characteristic]

The vaccine is a preparation of capsular polysaccharide antigens purified from the cultures of *Neisseria meningitidis* group A and C and bound with tetanus toxoid, then purified and adsorbed with aluminum hydroxide adjuvant. The final product is milky white suspension. It should not contain clumps that cannot disperse after shaking.

Active ingredients: *Neisseria meningitidis* group A and C capsular polysaccharide

Excipients: aluminum hydroxide, sodium chloride

Diluent: sterilized water for injection

[Eligibles]

Infants above 3 months and children

[Indications and Use]

The vaccine can induce humoral immune response in recipients following immunization. It is used to prevent infectious diseases caused by *Neisseria meningitidis* group A and C, for instance cerebrospinal meningitis and pneumonia. It can not prevent infections caused by other pathogenic bacteria and neither can it prevent meningitis and pneumonia of other causes.

[Strength]

0.5 ml per single prefilled syringe. Each single human dose is 0.5ml containing tetanus toxoid conjugated to meningococcal group A and C polysaccharide 10 μ g respectively.

[Administration and Dosage]

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- (1) Shake well before use.
- (2) The vaccine should be injected subcutaneously at deltoid insertion area of the lateral upper arm, each human dose is 0.5ml
- (3) Immunization schedule:
 - Infants at 3-12 months of age: primed with three doses at interval of one month;
 - Children at 1-2 years of age: primed with two doses at interval of one month;
 - Children over 3 years or adults: primed with one dose.

[Adverse Reactions]

Common adverse reactions:

- (1) Within 24 hours after vaccination, there might be pain and haphalgnesia at injection site, and swelling, induration and pressing pain may occur. Local itching may occur occasionally. Most of the reactions can be relived spontaneously within 2 to 3 days. Treat according to the symptoms if necessary.
- (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.
- (3) Irritability, sleepiness, vomiting, diarrhea and anorexia could occur occasionally.

Rare adverse reactions:

- (1) Severe fever: symptomatic treatment should be given to prevent febrile seizures.
- (2) 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 resuscitated and treated with epinephrine injection
- (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.

[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 to this vaccine or any other component of the vaccine, especially tetanus toxoid.
- (3) Subjects with severe heart diseases, hypertension, hepatic or renal diseases and active tuberculosis or HIV infection.
- (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, allergies and lactating women.
- (2) Shake well before use. Do not use the vaccine if the container shows abnormalities, such as crack, foreign matters, clumps cannot disperse after shaking, unclear label and expired.
- (3) The optimum immune response of the vaccine may be affected in individuals receiving

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immunosuppressive therapy or immunosuppressive 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) This vaccine has not been studied in clinical trials of simultaneous vaccination with other vaccines and whether there is interference with other vaccines is unknown. Simultaneous vaccination should be avoided so as not to affect vaccine immunity.

(6) In any case, the tetanus toxoid in this vaccine cannot be used as a substitute for routine tetanus toxoid immunization.

(7) Prohibit to freeze

[Storage]

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

[Packaging]

prefilled syringe, 20µg / 0.5ml / syringe, 1 syringe / box.

[Self Life]

24 months.

[Product Standard]

YBS00852021

[Product License Number]

GYZZ S20181000

[Marketing Authorization Holder and Address]

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