Instructions for Group A and C Meningococcal Polysaccharide Vaccine

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

【Name】

Generic name: Group A and C Meningococcal Polysaccharide Vaccine

English name: Group A and C Meningococcal Polysaccharide Vaccine

【Constituents and Characters】

This vaccine is made by mixture of group A and C Neisseria meningitides capsular polysaccharide antigens, which are extracted and purified through the cultures of Neisseria meningitides group A and C, respectively, with lactose as stabilizer for final lyophilization. The finished product is white and loose cake, can be easily dissolved with diluent (sterile water for injection) to be clear liquid.

Active Ingredients: Group A and C meningococcal polysaccharide

Other Composition: Lactose, Sodium Chloride

Diluent: Sterile water for injection

【Eligibles】

For 2 years old of age and older.

【Action and Use】

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

【Presentation】

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

【Administration Schedule and Dosage】

(1) Reconstitute the vaccine with the accompanying diluent according to indicated amount. With gentle shaking the dried cake is easily dissolved. After reconstitution the vaccine should be used immediately.

(2) The vaccine shall be injected subcutaneously into lateral upper arm.

(3) A single dose of 0.5ml should be administered only once for each human. Immunization shall be completed before the epidemic season of cerebrospinal meningitis.

【Adverse Reactions】

Common adverse reactions:

(1)The vaccine may cause pain, tenderness, mild or moderate swelling, inflammatory cell infiltration at the injection site within 24 hours of vaccination. In most cases, they spontaneously resolve within two to three days without further medical attention.

(2)Transient fever may occur after vaccination, most of which are mild, can be relieved spontaneously after1-2 days without further medical attention. Symptomatic treatment can be given to those with moderate fever or fever lasting for more than 48 hours.

Rare adverse reactions:

(1) Severe fever reaction: Symptomatic treatment shall be given to prevent febrile convulsion.

(2) Severe redness or swelling at the injection site or other complications: Symptomatic treatment shall be given.

Extremely rare adverse reactions:

(1) Anaphylactic rash: Rash may occur with 72 hours after vaccination. Once occurred, timely antianaphylactic treatment shall be given.

(2) Anaphylactic shock: Anaphylactic shock may occur within one hour after vaccination. Emergency treatment including injection with adrenaline shall be given promptly.

(3) Allergic purpura: Antianaphylactic treatment with corticosteroid should be given. If the treatment is inappropriate or delayed, purpura nephritis may be complicated.

(4) Angioneurotic edema and allergic neuritis may occur occasionally.

(5) Allergic exfoliative dermatitis cases have been reported occasionally.

【Contraindications】

(1) Individuals with known allergic reactions to any component of the vaccine.

(2) Individuals with acute diseases, severe chronic diseases, fever or during acute attack of chronic diseases.

(3) Individuals with encephalopathy, uncontrolled epilepsy, or other progressive neurological diseases.

【Precautions】

(1) The vaccine should be used with caution to individuals with: family or individual convulsion history, chronic diseases, history of epilepsy, allergic constitution or nursing women.

(2) Do not use the vaccine if the container shows abnormalities, such as crack, illegible label and turbidity after reconstitution.

(3) Adrenaline should be available for first aid in case of severe anaphylactic reactions. The recipients shall be observed for at least 30 minutes on site after injection.

(4) Should not be frozen.

【Storage】

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

【Packaging】

1 ml vial. Each vial of lyophilized vaccine is accompanied with one vial of 0.5ml diluent.

【Shelf Life】

The shelf life is 24 months. The expiry date of the vaccine is indicated on the label and packaging.

【Standard】 YBS00062012

【Registration Number】 S20120004

【Manufacturer】

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