Group A and Group C Meningococcal Conjugate Vaccine

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

Drug name
Group A and Group C Meningococcal Conjugate Vaccine

Constituents and characters
The vaccine is a lyophilized vaccine of Meningococcal capsular polysaccharide antigen, via polysaccharide activation and derivatisation covalently bound to tetanus toxoid protein.
The Meningococcal capsular polysaccharide is obtained from *Neisseria meningitidis* (Meningococcus) serogroup A strain 29201 and Meningococcus serogroup C strain 29205 individually through fermentation and purification. The conjugate is mixed at certain proportion then lyophilized with the proper stabilizer.

1 dose (0.5 mL) contains:
Group A Meningococcal Polysaccharide……10 μg
Group C Meningococcal Polysaccharide……10 μg
Tetanus toxoid protein……33~120 μg
Lactose ……3~5 mg
Sodium Chloride ……3.75~4.75 mg
Diluent: Sterile water for injection
This vaccine is presented as a white loose pellet, after reconstituted with diluent, the vaccine shall immediately turn into a clear, colorless solution.

Eligibles
Infants and children at the age of 3 months to 5 years.

Action and use
The vaccine is indicated for the active immunization of organism, especially for the prevention for infants under the age of 2 years from diseases caused by Meningococcal Group A, C, such as cerebrospinal meningitis and septicemia (general infection).
The vaccine does not prevent diseases caused by other serotypes of Meningococcal nor infection caused by pathogen causing meningitis or septicemia.

Specification
20 μg/0.5 mL/vial, 0.5 mL per single human dose. Each dose of vaccine contains 10 μg of each polysaccharide of group A and group C conjugated with tetanus toxoid respectively.

Administration and dosage
(1) Reconstitute the vaccine with the accompanying diluents. Shake well and inject immediately. Each singe human dose is 0.5 mL.
(2) The vaccine should be administered intramuscularly at the deltoid area of the lateral upper arm.
(3) According to the domestic clinical trial results, recommended immunization schedule for the vaccine is as follows:
Infants at the age of 3 to 12 months shall be given three doses (0.5 mL per dose) from age of 3 months, at intervals of one month.
Infants at the age of 13 to 24 months should follow recommended schedule of infants aged 3 to 12 months.
Children at the age of 2 to 5 years shall be given one dose (0.5 mL).
Booster dose: The need for, or timing of a booster dose of the vaccine has not yet been determined.

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Adverse reactions
Adverse reactions following vaccination are fever, rash. Pain, mild redness, swelling or pruritus may occur at the injection site, and usually resolved spontaneously.
Very rare systemic reactions are reported as headache, drowsiness, fatigue, dysphoria, gastrointestinal discomfort, etc.

Contraindications
This vaccine should not be administered to subjects as following:
- Subjects with known hypersensitivity to any component of the vaccine, especially to tetanus toxoid, or subjects who have had an allergic reaction after previous administration of the vaccine.
- Subjects with known epilepsy, convulsion or allergic history.
- Subjects with brain, kidney, heart disease, active tuberculosis and HIV infection.
- Subjects with acute infectious disease and fever.

Precautions
- Before administration, all appropriate precautions should be taken to prevent severe allergic reactions. When allergic reactions happen, the patient should see a doctor as soon as possible.
- Do not inject intravenously and ensure the needle not to enter a blood vessel.
- Check the packaging, label, appearance and expiration date of the vaccine before use. Do not use the vaccine if the container shows abnormalities, such as crack, loose stopper, illegible label, foreign matters, discoloration or exceeding the expiration date.
- The vaccine should be administrated immediately once opened.
- In any case, the routine immunization of tetanus toxoid can not be replaced by the vaccine.
- There is no clinical trial data regarding simultaneous administration of this vaccine with other vaccines. The interaction information is not clear, so considering the expected immune response, it is recommended to avoid administering vaccines simultaneously.

Storage
The vaccine should be stored and shipped at 2°C to 8°C; protect from light.

Packaging
Pack of 1 mL vial. 20 vials per box.

Validity period
The expiry date of the vaccine is 24 months. Please use within the expiration date indicated on the label and package.

Standard for implementation
YBS00102009

Product registration number
S20090003

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