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ACYW135 Meningococcal Polysaccharide Vaccine

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

[Drug Name]
Generic Name: Group ACYW135 Meningococcal Polysaccharide Vaccine
Trade Name: Menwayc
English Name: Group ACYW135 Meningococcal Polysaccharide Vaccine
Chinese Pinyin: ACYW135 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, C, Y and W135 respectively and lyophilized after addition of an appropriate stabilizer. The final product looks in a white loose powder shape. It shall turn into a clear liquid after reconstitution.
Active ingredients: Group A, C, Y, W135 Neisseria meningitides capsular polysaccharide
Excipients: lactose, sodium chloride
Diluent: sterilized water for injection

[Eligibles]
At present, the vaccine is only recommended to be used in the high-risk population, children over two years old and adults under the following conditions:

1. People traveling to or living in high risk areas, e.g. the Sahara region of Africa (epidemic area of Neisseria meningitidis group A, C, Y, W135 infection).
2. People who are engaged with laboratory work or vaccine manufacturing and may be exposed to Neisseria meningitidis group A, C, Y, W135 through air.
3. High risk groups in the area of Neisseria meningitidis group A, C, Y, W135 infection outbreak predicted by the Center for Disease Control and Prevention under the Ministry of Health based on epidemiological investigation.

[Indications and Use]
The vaccine is used to prevent epidemic cerebrospinal meningitis caused by Neisseria meningitidis group A, C, Y, W135.

[Strength]
After reconstitution, it shall be 0.5ml per vial. Each single human dose is 0.5ml containing 50μg of group A, C, Y, W135 polysaccharide respectively.

[Administration and Dosage]
(1) Reconstitute the vaccine with the acoompanying diluent 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 lateral upper armafter disinfection of the aforementioned skin area.
(3) Dosage: 0.5ml per human dose for single use.

(4) Primary immunization and doses: one dose. The immunization shall be completed before meningococcal epidemic season.
(5) Booster immunization (recommended in foreign countries): For the high risk individuals in epidemic areas, especially children vaccinated for the first dose before 4 years old, if they are under continuous high risk conditions, booster immunization shall be considered 2 to 3 years after the primary immunization. Although whether the older children and adults need the booster immunization is still to be determined, if the antibody level deceases quickly 2 to 3 years after the primary immunization, booster immunization shall be considered 3 to 5 years after primary vaccination.

[Adverse Reactions]
Based on the clinical trial results obtained from 840 domestic subjects vaccinated with this vaccine, the possible adverse reactions are as following:
According to the incidence rate of adverse reactions recommended by Council of International Organizations of Medical Sciences (CIOMS), it is very common (≥10%), common (1%~10%, including 1%), uncommon (0.1%~1%, including 0.1%), rare (0.01%~0.1%, including 0.01%) and very rare (<0.01%).
Local adverse reactions:
Common: pain, swelling
Rare: induration, pruritus
Systematic adverse reactions:
Very common: fever
Common: agitation, drowsiness, headache, stomachache
Rare: loss of appetite, vomiting, diarrhea
The above adverse reactions were mainly mild and moderate, and most of them could be relieved spontaneously and disappeared within 72 hours. In case of adverse reactions not mentioned above, please contact your doctor in time.

[Contraindications]
(1) Subjects with known allergic reactions to this vaccine or any other component of the vaccine.
(2) Subjects with epilepsy, encephalopathy and history of allergy.
(3) Subjects with renal diseases, heart diseases and active tuberculosis or HIV infection.
(4) Subjects with acute infections or chronic diseases at stage of acute attack.
(5) For this vaccine, no reproductive toxicity test among pregnant women and animals has been performed and influence on fetuses is unknown. Pregnant women should not use this vaccine, especially in the first trimester.

[Precautions]
(1) Checked the vial prior to use. Do not use the vaccine if the container shows any crack, stopper loose or abnormalities after reconstitution.
(2) For each container, it must be used up for once according to the specified human dose after reconstitution. If failed to be used immediately, it shall be stored no more than 30 minutes.
(3) Particular attention should be paid to avoid intradermal, intramuscular or intravenous injection of this vaccine since clinical safety and efficacy of those three routes have not been confirmed.
(4) Considering accumulation of bacterial endotoxin, the vaccine must not be injected simultaneously with whole cell pertussis vaccine or whole cell typhoid vaccine.
(5) It is not known whether the vaccine will be excreted with breast milk. Yet given the facts that multiple drugs can be excreted with breast milk, particular caution should be given when using the vaccine to lactating women.
(6) If the vaccine is immunized subjects with immunodeficiency or those receiving immunosuppressive therapy, no immune response will be induced.
(7) The vaccine cannot be used for treatment of patients with Neisseria meningitidis infection, neither can it be used to protect cerebrospinal meningitis caused by other pathogens including Neisseria meningitidis group B.
(8) This vaccine cannot provide short-term prevention for infants and children below 2 years of age but can protect infants aged 3 months and above against including Neisseria meningitidis group A for a short term.
(9) As with other vaccines. This vaccine cannot provide 100% protection for susceptible groups.
(10) Adrenalin injection (1:1000) treatment must be available to manage possible anaphylactic reactions following administration of the vaccine.

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

[Packaging]
Vial,200μg/vial, 1 vial/box:One box contains one vaccine diluent, in pre-filled syringe package, 0.5ml/vial.

[Self Life]
24 months.

[Product Standard]
YBS00872021

[Product License Number]
GYZZ S20070025

[Marketing Authorization Holder and Address]
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