Group ACYW135 Meningococcal Polysaccharide Vaccine

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

【DESCRIPTION】

This vaccine is a lyophilized vaccine of purified meningococcal A, C, Y and W135 Neisseria meningitides capsular polysaccharide antigens. The finished product is mixed at certain proportion then lyophilized with the proper stabilizer. The vaccine satisfies recommendations given by WHO in relation to meningococcal polysaccharide vaccines.

The group ACYW135 meningococcal polysaccharide vaccine is provided as 1-dose presentation. The lyophilized polysaccharide vaccine is reconstituted just before use with the contents of one vial of diluent (WFI). The vaccine is presented as a white loose pellet. After reconstitution with diluent, the vaccine shall immediately turn into a clear, colorless solution.

1 dose contains:

Group A Meningococcal Polysaccharide.....50μg
Group C Meningococcal Polysaccharide.....50μg
Group Y Meningococcal Polysaccharide.....50μg
Group W135 Meningococcal Polysaccharide.....50μg
Lactose.....4mg
Sodium Chloride.....4.25mg
Diluent: Sterile water for injection.....0.5mL

【ELIGIBLES】

Children of 2 years old of age and above who are at high risk of getting this disease:

(1) People who are travelling to and living in high risk areas, for example, Sub-Saharan Africa (Group A, C, Y, W135 meningococcal epidemic area).

(2) People who are working with group A, C, Y, W135 meningococcal in the laboratory or in vaccine workshops may be infected from the air.

(3) According to epidemiological investigation, by the ministry of Health and the Centers for Disease Control prediction of Y and W135 meningococcal outbreaks areas of high risk population.

【ACTION AND USE】

Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W135 Combined, is indicated for active immunization for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y, and W135. It is approved for use in persons 2 years of age and older. It is not indicated for the prevention of meningitis caused by microorganisms other than N. meningitidis serogroups A, C, Y, and W135. It is neither indicated for treatment of meningococcal infections.

【SPECIFICATION】

200μg/0.5mL/vial after reconstitution, 0.5mL per single human dose. Each dose of vaccine contains 50μg of group A, C, Y and W135 meningococcal polysaccharide, respectively.

【ADMINISTRATION 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.

(4) Re-vaccination: High risk individuals in infectious area, especially children below 4 years old after the first vaccination, if sustained at high risk, revaccination should be administrated after 2~3 years from the first vaccination. Although, it has not been confirmed the necessity for the older children and adults to be re-vaccinated, if the antibody level has rapidly declined after the first vaccination, then re-vaccination is considered after primary immunization within 3-5 years.

【ADVERSE REACTIONS】

Local reactions at injection site: slight pain at injection site may occur within 24 hours after vaccination. Occasionally, mild swelling, redness or itching may occur. In most cases, they spontaneously resolve within two to three days without further medical attention. Systemic reaction: transient fever may occur after vaccination, most of which are mild (below 37.5℃), can be relieved spontaneously after 1-2 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 may occur severe fever reaction, symptomatic treatment shall be given to prevent febrile convulsion. Besides, fever, fatigue, drowsiness, myalgia, abdominal pain, loss of appetite, irritability and diarrhea may occur after vaccination, very few may have vomiting or rash. In most cases, they spontaneously resolve. Symptomatic treatments shall be given according to the specific circumstances.

Adverse Reaction Rate (%)

Adverse reactions	Studygroup (N=600)		
	Mild%	Moderate%	Severe%
Local	30.0	2.0	0.16
Systemic			
Fever*	21.67	7.33	0.33
Headache	6.67	0.5	0
Fatigue	4.50	0.17	0
Drowsiness	3.17	0	0.17
Myalgia	2.00	0.17	0
Abdominal pain	2.17	0	0
Loss of appetite	1.83	0	0
Irritability	1.33	0.33	0
Diarrhea	1.33	0.17	0
Vomiting	0.33	0.17	0
Rash	0.17	0	0.17

*Mild: 37.1~37.5℃, Moderate: 37.6~39.0℃, Severe: >39.0℃

【CONTRAINDICATIONS】

This vaccine should not be administered to:

(1) Individuals with known epilepsy, convulsion, brain disorder or allergic history.

(2) Individuals with kidney and heart disease, active tuberculosis.

(3) Individuals with acute infectious disease and fever.

(4) Reproductive toxicity hasn't been studied in pregnant women or animals, it is unknown whether this vaccine has impact on fetus. Therefore, pregnant women are forbidden to use this vaccine, especially in the first three months of pregnancy.

【PRECAUTIONS】

(1) It should be inspected visually for container integrity, particulate matter and discoloration prior to administration. Do not use after the expiration date. Do not use the vaccine if the container shows abnormalities, such as crack, illegible label or turbidity after reconstitution.

(2) The vaccine should be administrated immediately once opened, if it's not used immediately, the vaccine should be disposed after 30 minutes.

(3) Pay special attention to avoid the vaccine being injected intradermally, intramuscularly or intravenously as such routes of administration have not been studies via clinical trials to be ensure safety and efficacy.

(4) Due to endotoxin superposition, this vaccine shall not be co-administered with pertussis vaccine or typhoid vaccine.

(5) It is not known whether this vaccine can be excreted in human milk. Due to many drugs can be excreted with human milk, it should be pretty cautious to use this vaccine on breast-feeding women.

(6) Persons who are immunosuppressed, including persons receiving immunosuppressive therapy, will have no immune response to vaccine.

(7) This vaccine is not indicated for treatment of meningococcal infections, nor be able to protect against cerebrospinal meningitis caused by infection of other strains of meningococcus including group B meningococcus; The vaccine cannot provide short-term prevention for infants and children under 2 years old. The vaccine cannot provide 100% protection for susceptible population.

(8) Appropriate medical treatment such as epinephrine or other drugs shall be available to manage possible anaphylactic reactions following administration of the vaccine, subjects after injection should be observed for at least 30 minutes.

【STORAGE】

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

【PACKAGING】

1mL 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】 YBS00052012

【APPROVAL NUMBER】 S20120003

【MANUFACTURER】

Enterprise: Yuxi Walvax Biotechnology Co., Ltd.
Address: No. 83 South Dongfeng Road, High-tech Zone, Yuxi, Yunnan Province, China
Zip Code: 653100
Tel: +86-877-2076210
Fax: +86-877-2076918
Website: http://www.walvax.com

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YUXI WALVAX BIOTECHNOLOGY CO., LTD.