MENOMUNE® ACYW-135

Meningococcal polysaccharide vaccine Group A, Group C, Group Y and Group W-135

Description

The vaccine is a freeze-dried preparation of the group specific antigens from *Neisseria meningitidis*, Group A, Group C, Group Y and Group W-135. The diluent contains no preservative. After reconstitution with the accompanying diluent, each 0.5 mL dose contains 50 mcg of polysaccharide from each of Group A, C, Y and W-135 in isotonic sodium chloride solution. Each dose of the vaccine contains 2.5-5 mg of lactose. When reconstituted, the vaccine is a clear colourless liquid.

Uses

Pharmacology

Vaccination with the meningococcal polysaccharides induces the production of bactericidal antibodies which are group specific. That is, the group A polysaccharide induces antibodies only against Group A, and not against any other serogroups.

Antibody responses to each component of Menomune® have been similar to the responses of the individual polysaccharides administered alone.

A study using 4 lots of Menomune® in 150 adults showed at least a four-fold increase in bacterial antibodies to all four antigen serogroups in greater than 90% of the subjects. In children aged 2 years and older seroconversion by bacterial antibody was seen in Group A-72%, Group C-58%, Group Y-90% and Group W-135-82%. Antibody persistence at 27 months was well maintained for groups A, C and W-135, but seroconversion had dropped to 64% in Group Y.

In another study, antibodies were detected 5 years post-vaccination by the ELISA method, however the significance of these antibody levels for protection is unknown. In children antibody persistence is of a shorter duration than adults.

Although clinical efficacy of A and C group specific antibodies has been demonstrated, there is no available data on the protective efficacy of antibodies to the Y and W-135 polysaccharide. In asplenic patients, although acceptable antibody response to group A and C polysaccharides was demonstrated, no data exists on protective efficacy in this group.

Indications

Menomune® ACYW-135 is indicated for active immunisation of adults and children older than 2 years against disease caused by *Neisseria meningitidis* Groups A, C, Y and W-135, the major manifestation being meningococcal meningitis. Vaccination may be considered for the following individuals:

- Travellers to countries recognised as having highly endemic or epidemic disease.
- Control of epidemics of infection caused by *Neisseria meningitidis* groups A, C, Y and W-135 in confined communities.

- Individuals at particular high risk of acquiring meningococcal infection, including persons with anatomic or functional asplenia.
- Close contacts of persons with meningococcal disease due to groups A, C, Y and W-135, as an adjunct to appropriate chemoprophylaxis.

Contraindications

Hypersensitivity to any component of the vaccine is a contraindication to the use of this vaccine. Vaccinating with Menomune® ACYW-135 should be deferred in the presence of any acute illness.

Precautions

A review of the patient's history with respect to possible sensitivity to the vaccine should occur prior to vaccination. As with any injection of biological materials, adrenaline injection (1:1000) should be available for immediate use should an anaphylactic or other allergic reactions occur.

Do not inject this vaccine intradermally, intramuscularly or intravenously. Individuals receiving corticosteroids or other immunosuppressive drugs may not develop an optimum immunologic response. Antibody responses were markedly lower in asplenic patients with lymphoid tumours than asplenia due to other causes. Immune response may be impaired in acute malaria.

This vaccine will not stimulate protection against infections caused by organisms other than Groups A, C, Y and W-135 meningococci. This vaccine gives no protection against infection caused by Group B meningococci.

As with many vaccines, protection (against groups A, C, Y and W-135 meningococci) may not be conferred in 100% of patients.

Use In Pregnancy (Category B2)

There is no convincing evidence of risk to the foetus from immunisation of pregnant women using an inactivated bacterial vaccine. Animal reproductive studies have not been conducted with Menomune®. It is also not known if Menomune™ can cause foetal harm when administered to pregnant women or can affect reproduction capacity. In cases of substantial risk of exposure, benefit to risk considerations may necessitate vaccination.

Use In Children

Menomune® is recommended for use in children over 2 years of age. Immunogenicity and safety have not been demonstrated in infants and children less than 2 years of age.

Interactions

Menomune® should not be given at the same time as whole-cell pertussis or whole-cell typhoid vaccines due to the possible additive frequency and severity of adverse reactions from the combined endotoxin content of the individual vaccines.

Adverse Reactions

Adverse reactions to meningococcal vaccine are usually mild and infrequent. In clinical studies localised erythema and tenderness commonly occur and last 1 to 2 days. Mild systemic reactions including temperature greater than 38°C (approximately 3%), headache, malaise and fatigue, were reported less frequently. Rarely reported reactions include urticaria, wheeze, angioedema and severe local reactions. Transient neurological reactions have also been reported rarely with the Group A polysaccharide but a causal association with the vaccine has not been established.

Dosage And Administration

The vaccine is to be reconstituted using only the accompanying diluent.

Primary immunisation: For both adults and children, the immunising dose is a single injection of 0.5 mL given subcutaneously.

Revaccination: Data on persistence of antibody response is limited and the optimal time for revaccination has not been established.

In adults it appears likely that the antibody response will last for at least 2 years, possibly longer. In children, antibody persistence is of a shorter duration than adults.

Overdosage

Not applicable

Package Quantities

Storage

Store at 2° to 8°C. Refrigerate. Do not freeze. Use within 24 hours after reconstitution.

Presentation

Injection 0.5 mL dose: 1's

Box of 1 single dose vial of lyophilised vaccine and 1 vial of diluent.

Medicine Classification

Prescription Medicine

Manufacturer

Sanofi Pasteur Inc
Swiftwater, PA 18370, USA

Distributor

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1 November 2007