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*, serogroups A, C, Y and W-135.

When reconstituted, the vaccine is a clear colourless liquid.

After reconstitution with the accompanying diluent, each 0.5 mL dose of vaccine contains:

Active ingredients:

- Meningococcal polysaccharide Group A 50 µg/dose
- Meningococcal polysaccharide Group C 50 µg/dose
- Meningococcal polysaccharide Group Y 50 µg/dose
- Meningococcal polysaccharide Group W-135 50 µg/dose

Excipients:

- Lactose 2.5 mg to 5.0 mg/dose
- Sodium chloride 4.25 to 4.75 mg/dose
- Water for injection

No preservative is added.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (variant Creutzfeldt-Jakob disease, considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

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® ACYW-135 have been similar to the responses of the individual polysaccharides administered alone.

A study using 4 lots of Menomune® ACYW-135 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% for Group Y.

In another study, antibodies were detected 5 years post-vaccination by the enzyme-linked immunosorbent assay (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 group-specific antbodies to the A and C polysaccharides has been demonstrated, there is no available data on the protective efficacy of antibodies to the Y and W-135 polysaccharides. In asplenic patients, although acceptable antibody responses to groups A and C polysaccharides were demonstrated, no data exists on protective efficacy in this population.

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 febrile or acute illness.

Precautions

However, a minor febrile or non-febrile illness, such as a mild upper respiratory infection, is not usually a reason to postpone immunisation.

The stopper to the vial contains dry natural latex rubber that may cause allergic reactions.

A review of the patient's history with respect to possible sensitivity to the vaccine should occur prior to vaccination. Adrenaline/epinephrine and other appropriate agents used for the control of immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur.

Do not inject this vaccine intradermally, intramuscularly or intravenously.

Persons who are immunosuppressed, including persons receiving immunosuppressive therapy,may have a diminished immune response to Menomune® ACYW-135 vaccine. Antibody responses were markedly lower in patients with asplenia due to lymphoid tumours than patients with 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 all vaccines, protection (against Groups A, C, Y and W-135 meningococci) may not be conferred in 100% of patients.

Effect on Fertility

It is not known if Menomune ACYW-135 vaccine can affect reproduction capacity.

Use In Pregnancy (Category B2)

Animal reproductive studies have not been conducted with Menomune® ACYW-135 vaccine. It is also not known if Menomune® ACYW-135 vaccine can cause foetal harm when administered to a pregnant woman.Menomune® ACYW-135 vaccine should be given to pregnant women only if clearly needed, and following an assessment of the risks and benefits.

Use In Lactation

It is not known whether this vaccine is excreted in human milk. Caution must be exercised when Menomune® ACYW-135 vaccine is administered to a nursing mother.

Paediatric Use

Menomune® ACYW-135 vaccine 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.

Use in the Elderly

Clinical trial experience with Menomune ACYW-135 vaccine in the elderly is limited.

Genotoxicity

No genotoxicity studies have been conducted with Menomune ACYW-135 vaccine.

Carcinogenicity

No carcinogenicity studies have been conducted with Menomune ACYW-135 vaccine.

Effects on Laboratory Tests

Interference of Menomune ACYW-135 vaccine with laboratory tests has not been studied.

Interactions with other medicines

Immunosuppressive therapies may reduce the immune response to Menomune® ACYW-135 vaccine.

Adverse Effects

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.

Post-Marketing Experience

Based on post-marketing surveillance, the following adverse events have been reported during the commercial use of Menomune ACYW-135 vaccine.

Renal and Urinary Disorders

- IgA nephropathy

Immune System Disorders

- Allergic reactions, such as urticaria, pruritus, breathing difficulty, rash, and angioedema

Nervous System Disorders

- Headache, vasovagal syncope, dizziness, paraesthesia, somnolence, irritability

Musculoskeletal and Connective Tissue Disorders

- Myalgia, arthralgia

Metabolism and Nutrition Disorders

- Decreased appetite

Gastrointestinal disorders

- Nausea, vomiting, diarrhoea

General Disorders and Administration Site Conditions

- Fever, injection site reaction, malaise, asthenia, chills, fatigue

Dosage And Administration

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.

The package contains a vial of lyophilised vaccine and a vial of diluent. The lyophilised vaccine should be a white or off-white colour to a light beige colour. The diluent is a clear liquid. The vials and packaging should be inspected prior to use for evidence of leakage or a faulty seal. If either of these conditions exists, the vaccine should not be administered.

After removing the "flip-off" caps, cleanse the vaccine and diluent vial stoppers with a suitable germicide. Do not remove the vial stoppers or metal seals holding them in place. Using a suitable sterile needle and syringe and aseptic technique, withdraw 0.6 mL of the supplied diluent and inject into the vaccine vial. Swirl the vial until the vaccine is thoroughly dissolved. When reconstituted, the vaccine is a clear, colourless liquid. Inspect Menomune ACYW-135 vaccine visually for particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.

Using a suitable sterile needle and syringe and aseptic technique, withdraw and administer a 0.5 mL dose subcutaneously. The preferred site of administration is the deltoid region.

Do not administer intravenously, intramuscularly, or intradermally.

Used needles should never be recapped but disposed of properly.

The vaccine should not be combined through reconstitution or mixed with any other vaccine.

The vaccine should be used immediately after reconstitution.

Overdosage

Not applicable

Presentation and Storage Conditions

Presentation

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

Storage conditions

Store at 2° to 8°C. Refrigerate. Do not freeze.

Name and Address of the Sponsor

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