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H 33" W 24" L 58"
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Options: Tilt, Door

Safari Camo:
H 35" W 28" L 68"
The Safari Camo is ready for action. A three step walk up will save your back and speed up exams. Rounded corners make for a safe trip. Add locks to protect valuable instruments.
Options: Tilt, Island or Wall

Infant 100:
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The Infant 100 is great for exams or a changing table. 3" round steel legs provide a stable and level base. The top is fully enclosed with rounded corners. A 2" thick pad is removable and replaceable. Add drawers for more storage.
Options: Stadiometer

MC 40:
H 35" W 29" L 25"
This colorful cart is sure to brighten any exam. It features four drawers that lock with one key. The top has a 2" lip to prevent spillage. Locking 4" swivel casters provide mobility.
Options: Doors

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Goodtime Medical
5410 W. Roosevelt Rd.
Chicago, IL 60644
773-626-5000
Fax 773-626-5015
Menomune® – A/C/Y/935
Meningococcal Polysaccharide Vaccine
Groups A, C, Y and W-135 Combined

**CLINICAL PHARMACOLOGY**

**Vaccine efficacy**

The immunogenicity and clinical efficacy of serogroup A and C meningococcal vaccines have been well established. The serogroup A polysaccharide induces antibody in some children as young as 3 months of age, although a response comparable with that among adults is not achieved until 4 or 5 years of age; the serogroup C component is immunogenic in recipients who are less than 18 to 24 months of age. The serogroups A and C vaccines have demonstrated estimated clinical efficacies of 85% in 100% in older children and adults, respectively, who are useful in controlling epidemics. Serogroups Y and W-135 polysaccharides are safe and immunogenic in adults and in children greater than 2 years of age. Although clinical protection has not been documented with these polysaccharides, they induce bactericidal antibody. The antibody responses to each of the four polysaccharides in the quadrivalent vaccine are serogroup specific and independent.

**INDICATIONS AND USAGE**

Menomune® – A/C/Y/935 is indicated for active immunization against invasive meningococcal disease caused by these serogroups. Menomune® – A/C/Y/935 may be used to prevent and control outbreaks of serogroup C meningococcal disease. Routine vaccination is recommended for the following high-risk groups: 1. Deficiencies in late complement components (C3, C5-C9), 2. Functional or actual asplenia, 3. Persons with laboratory or industrial exposure to N. meningitidis aerosols, 4. Travelers to, and residents of, hyperendemic areas such as sub-Saharan Africa. The American College Health Association (ACHA) also recommends students consider vaccination to reduce the risk for potentially fatal meningococcal disease. Vaccinations also should be considered for household contacts of persons with meningococcal disease and for medical and laboratory personnel at risk of exposure to meningococcal disease. Protective antibody levels may be achieved within 7 to 10 days after vaccination. Menomune® – A/C/Y/935 is not indicated for infants and children younger than 2 years of age except as short-term protection of infants 3 months and older against Group A.

For persons remaining at high-risk, especially children who were first vaccinated at <4 years of age, revaccination may be indicated. (See DOSAGE AND ADMINISTRATION section.)

**CONTRAINDICATIONS**

Immunization should be deferred during the course of any acute illness. It is a CONTRAINDICATION to ADMINISTER MENOMUNE® – A/C/Y/935 TO INDIVIDUALS KNOWN TO BE SENSITIVE TO THIMEROSAL OR ANY OTHER COMPONENT OF THE VACCINE. FOR INDIVIDUALS SENSITIVE TO THIMEROSAL, ADMINISTER THE ONE DOSE PACKAGE SIZE AND RECONSTITUTE WITH THE 0.78 ML VIAL OF DILUENT THAT CONTAINS NO PRESERVATIVE.

**WARNING**

This product contains dry natural latex rubber as follows: The vaccine vial contains dry natural latex rubber. If the vaccine is used in persons receiving immunosuppressive therapy, the expected immune response may not be obtained. Menomune® – A/C/Y/935 should NOT be given at the same time as whole-cell pertussis or whole-cell typhoid vaccines due to combined endotoxin content.

**PRECAUTIONS**

**General**

Care is to be taken by the health-care provider for the safe and effective use of Menomune® – A/C/Y/935.

**EPIDEMIC MENINGOCOCCAL INFECTION (1:1000) MUST BE IMMEDIATELY AVAILABLE TO COMBAT UNEXPECTED ANAPHYLACTIC OR OTHER ALLERGIC REACTIONS.**

Prior to an injection of any vaccine, all known precautions should be taken to prevent adverse reactions.

Special care should be taken to avoid injecting the vaccine intradermally, intramuscularly, or intravenously since clinical studies have not been done to establish safety and efficacy of the vaccine using these routes of administration.

**Information for Patient**

Patients, parents or guardians should be fully informed of the benefits and risks of immunization with Menomune® – A/C/Y/935.

Patients, parents or guardians should be instructed to report any serious adverse reactions to their health-care provider.

As part of the patient's immunization record, the date, lot number and manufacturer of the vaccine administered should be recorded.

**Drug Interactions**

If Menomune® – A/C/Y/935 is administered to immunosuppressed persons or persons receiving immunosuppressive therapy, an adequate immunologic response may not be obtained.

**Cardiogenic, Mutagenesis, Impairment of Fertility**

Menomune® – A/C/Y/935 has not been evaluated in animals for its cardiogenic, mutagenic potentials or impairment of fertility.

**Pregnancy**

Reproductive Studies – Pregnancy Category C

Animal reproduction studies have not been conducted with Menomune® – A/C/Y/935. It is also not known whether Menomune® – A/C/Y/935 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Menomune® – A/C/Y/935 should be given to a pregnant woman only if clearly needed.

**Nursing Mothers**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Menomune® – A/C/Y/935 is administered to a nursing woman.

**Pediatric Use**

Safety and EFFECTIVENESS OF MENOMUNE® – A/C/Y/935 IN CHILDREN BELOW THE AGE OF 2 YEARS HAVE NOT BEEN ESTABLISHED.

**ADVERSE REACTIONS**

Adverse reactions to meningococcal vaccine are mild and consist principally of pain and redness at the injection site for 1 to 2 days. Pain at the site of injection is the most commonly reported adverse reaction, and a transient fever might develop in less than or equal to 2% of young children. Adverse events reported by 150 adults following vaccination with Menomune® – A/C/Y/935 are shown in Table 1. The subjects were observed for three weeks following vaccination. Local reactions reported within 48 and no significant systemic reactions were reported.

<table>
<thead>
<tr>
<th>TABLE 1 1 ADVERSE EVENTS (%) FOLLOWING VACCINATION OF 150 ADULTS WITH MENOMUNE® – A/C/Y/935</th>
<th>Reactions</th>
<th>Mild</th>
<th>Moderate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local</td>
<td>Pain</td>
<td>2.6</td>
<td>2.0</td>
</tr>
<tr>
<td>Tenderness</td>
<td>36.0</td>
<td>9.0</td>
<td></td>
</tr>
<tr>
<td>Diameter</td>
<td>&lt; 2 in.</td>
<td>≥ 2 in.</td>
<td></td>
</tr>
<tr>
<td>Erythema</td>
<td>3.6</td>
<td>1.2</td>
<td></td>
</tr>
<tr>
<td>Induration</td>
<td>4.4</td>
<td>1.2</td>
<td></td>
</tr>
</tbody>
</table>

Table:<br>Menomune® – A/C/Y/935 is shown in Table 1. The subjects were observed for three weeks following vaccination. Local reactions reported within 48 hours and no significant systemic reactions were reported.

**DOSAGE AND ADMINISTRATION**

Menomune® – A/C/Y/935 should be injected into the vial containing the vaccine. Shake vial until the vaccine is dissolved. The medication dose is single injection of 0.5 ml administered subcutaneously.

**Primary Immunization**

For both adults and children, vaccine is administered subcutaneously as a single 0.5 ml dose. Protective antibody levels may be achieved within 7 to 10 days after vaccination.

**Revaccination**

Revaccination of a single 0.5 ml dose administered subcutaneously may be indicated for individuals at high-risk of infection, particularly children who were first vaccinated when they were less than 4 years of age; such children should be considered for revaccination after 2 or 3 years if they remain at high-risk. Although the need for revaccination in older children and adults has not been determined, antibody levels decline rapidly over 2 to 3 years, and if indications still exist for immunization, revaccination should be considered within 3 to 5 years. Simultaneous administration of Menomune® – A/C/Y/935 can be given concurrently with other vaccines at separate sites and separate syringes. However, due to the combined endotoxin content, the vaccine should not be administered at the same site as a whole cell pertussis or whole-cell typhoid vaccines. (See WARNINGS section.)

**HOW SUPPLIED**

Vial, 1 Dose, with 0.78 ml vial of diluent (contains NO preservative). Product No. 49281-489-01

Vial, 1 Dose (5 package) with 0.78 ml vial of diluent (5 package) (contains NO preservative). Product No. 49281-489-05

Vial, 10 Dose, with 6 ml vial of diluent (contains preservative) for administration with needle and syringe (NOT to be used with jet injector). Product No. 49281-489-91.

**STORAGE**

Store freeze-dried vaccine and reconstituted vaccine, when not in use, between 2°-8°C (35°-46°F). Discard remainder of multidose vials of vaccine within 35 days after reconstitution. The single dose vial should be used within 30 minutes after reconstitution.

**REFERENCES**


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Reference:
1. Data on file for DESITIN Original. Pfizer, Inc.
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