

## IMMUNIZATION PROTOCOL FOR PHARMACISTS

### MENINGOCOCCAL VACCINE

Revisions as 03/09

- ACIP recommends that MCV4 (Menactra™), recently FDA- approved for 2–55 years, be available for high-risk persons.
- MCV4 (Menactra™), is preferred among high-risk persons 18–55 years of age.
- MPSV4 (Menomune®) is recommended among high-risk persons >55 years of age.

#### I. **ORDER:**

1. Screen all adults 18 years and older for contraindications.
2. Provide a current Vaccine Information Sheet (VIS), answering any questions. <http://www.cdc.gov/vaccines/pubs/vis/default.htm>
3. Obtain a signed consent.
4. Give either 0.5 ml of tetravalent Meningococcal Conjugate vaccine (MCV4) (**Menactra™**) **intramuscularly (IM)** as a single dose (only to eligible persons ≥18 years old), or 0.5 ml of tetravalent Meningococcal Polysaccharide vaccine (MPSV4) (**Menomune®**) **subcutaneously (SC)** as a single dose (only to eligible persons ≥18 years old).
5. Give according to ACIP recommendations, age-appropriate schedule and high-risk situation.
6. MCV4 or MPSV4 can be administered concomitantly with other vaccines at different anatomic sites.

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Pharmacists Signature

Date

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| <b>II a. LICENSED TETRAVALENT MENINGOCOCCAL POLYSACCHARIDE VACCINE (MPSV4)</b>  |   |                             |  |
|---|---|-----------------------------|--|
| <b>Product Name</b>   | <b>Vaccine Components</b>   | <b>Acceptable Age Range</b> | <b>Thimerosal</b>                                |
| <b>Menomune®</b> <sup>1,2,3,4,5</sup><br>(Sanofi Pasteur)   | Each dose consists of 50 µg of each of 4 purified bacterial capsular polysaccharides, A, C, Y, and W-135. <sup>4</sup>  | ≥2 years                    | No<br>(single-dose vials)                        |
|   |   |                             | Yes<br>(in diluent of multi-dose vial),<br>0.01% |
| <b>II b. LICENSED TETRAVALENT MENINGOCOCCAL CONJUGATE VACCINE (MCV4)</b>  |   |                             |  |
| <b>Menactra™</b> <sup>3,4,6,7</sup><br>(Sanofi Pasteur)   | Tetavalent meningococcal conjugate vaccine containing capsular polysaccharide from serogroups A, C, Y and W-135 conjugated to 48 µg of diphtheria toxoid <sup>4</sup> | 2–55 years                  | No<br>(single-dose vials)                        |
| <p><sup>1</sup> Should not be given at the same time as whole-cell typhoid vaccine due to combined endotoxin content (per package insert). However, oral Vivotif Berna™ manufactured by Berna, and Typhim Vi™, manufactured by Aventis for IM use do not interfere with Menomune®.</p> <p><sup>2</sup> Single-dose vials should be used within 30 minutes after reconstitution, and multi-dose vials should be discarded within 35 days after reconstitution.</p> <p><sup>3</sup> If MPSV4 or MCV4 are administered to immunosuppressed persons, an adequate immunologic response may not be obtained.</p> <p><sup>4</sup> Does not include serogroup B, which is the most common serotype found in Oregon.</p> <p><sup>5</sup> <b>MPSV4</b> should be administered as a single 0.5-ml injection by the <b>SC route</b>.</p> <p><sup>6</sup> <b>MCV4</b> should be administered as a single 0.5-ml injection by the <b>IM route</b>.</p> <p><sup>7</sup> MCV4 must not be mixed with any vaccine in the same syringe.</p> |   |                             |  |

### III. RECOMMENDATIONS FOR USE

#### MCV4 (MENACTRA™)

##### **Routine vaccination is recommended for:**

- Adolescents 11–18 years of age.<sup>1</sup>
- These high-risk persons 2–55 years of age<sup>2</sup>:
  1. College freshman living in dormitories<sup>3</sup>
  2. Persons with terminal complement component deficiencies
  3. Persons with anatomic or functional asplenia
  4. Lab personnel who are routinely exposed to isolates of *N. meningitidis*
  5. Military recruits
  6. Travelers to or residents of sub-Saharan Africa’s “Meningitis Belt,” during December to June
  7. Visitors to Mecca in Saudi Arabia during annual Hajj; and
  8. Countries in which *N. meningitidis* is hyper-endemic or epidemic.<sup>4</sup>
- To control outbreaks of meningococcal disease.<sup>5</sup>

<sup>1</sup>Revised Recommendations of ACIP to vaccinate all persons aged 11–18 years with meningococcal conjugate vaccine. MMWR 2007; 56(31): 794–5.

<sup>2</sup> MCV4 is preferred among persons 2–55 years of age; MPSV4 is recommended among persons >55 years of age.

<sup>3</sup> May also be given to college students not living in dorms or to any adolescent upon request

<sup>4</sup> Contact a local travel clinic, health department, Centers for Disease Control and Prevention’s (CDC) travel line (877-394-8747) or [www.cdc.gov/travel/diseases/menin.htm](http://www.cdc.gov/travel/diseases/menin.htm) for the list of high-risk countries.

<sup>5</sup> An Outbreak is defined as the occurrence of three or more confirmed or probable cases of meningococcal disease during a period of ≤3 months, with a resulting primary attack rate of ≥10 cases per 100,000 population.

See MMWR 2005; 54(RR-7): 14.

**IV. VACCINE SCHEDULE**

**A. MCV4 (MENACTRA™) Vaccination Schedule for Healthy Adolescents<sup>1</sup>**

Dose: 0.5 ml

Route: intramuscularly (IM) preferably in deltoid

| <b>Number of Doses</b> | <b>Minimum age</b> | <b>Recommended age</b> | <b>Recommendation for revaccination</b> |
|------------------------|--------------------|------------------------|---|
| 1                      | 18 years           | 18 years               | None                                    |

**B. MCV4 (Menactra™) and MPSV4 (Menomune®) Vaccination Schedule for High-Risk Adolescents and Adults<sup>1,2</sup>**

Dose: 0.5 ml

Route: Menactra™ intramuscularly (IM) preferably in deltoid  
Menomune® subcutaneously (SC) in outer thigh or arm

| <b>Number of Doses</b> | <b>Minimum age</b> | <b>Recommended Age for immunization</b> | <b>Recommendation for revaccination<sup>2</sup></b>  |
|------------------------|--------------------|---|--|
| 1                      | 18 years           | 18 – 55 years <sup>3</sup>              | Revaccination should be considered 5 years following the 1st dose if patient remains at high risk for infection <sup>4</sup> |

<sup>1</sup>Protective level of antibody is usually achieved within 7-10 days of vaccination

<sup>2</sup>High-risk conditions and persons: terminal complement deficiency, functional or anatomic asplenia, 2 weeks before or 2 weeks after splenectomy, certain lab workers, and travelers to or residents of countries where *N. meningitidis* infection is hyperendemic or epidemic.

<sup>3</sup>Per ACIP, MCV4 is preferred for revaccination of persons 2–55 years of age who have previously been vaccinated with MPSV4; however, use of MPSV4 is acceptable in this age group. Additionally, MCV4 is preferred to MPSV4 for use among children 2–10 years of age for control of meningococcal disease outbreaks.

<sup>4</sup>For children aged 2–6 years ACIP recommends re-vaccination with MCV4 at 3 years interval. Further revaccination after receipt of MCV4 is not recommended at this time.

**V. CONTRAINDICATIONS**

1. A severe allergic (anaphylactic) reaction to thimerosal or any other vaccine component, including diphtheria toxoid (for MCV4) or to dry natural rubber latex for MCV4 and MPSV4. (MPSV4 stopper to vial contains dry natural latex rubber).
2. A severe allergic reaction following a prior dose of meningococcal vaccine

**VI. PRECAUTIONS**

1. Immunization should be deferred during the course of moderate or severe acute illness.
2. Pregnancy, breastfeeding and immunosuppression are **not** contraindications to vaccination.
3. Persons with a history of Guillain-Barré syndrome (GBS) might be at increased risk for GBS after MCV4 vaccination.<sup>1</sup>

<sup>1</sup> Persons for whom meningococcal vaccination is indicated but who have a history of GBS should discuss the decision to be vaccinated with their health-care provider. MPSV4 is an acceptable alternative for short-term (3–5 years) protection against meningococcal disease. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5631a3.htm>.

**VII. SIDE EFFECTS AND ADVERSE REACTIONS**

|  | <b>MCV</b> | <b>MPSV</b> |
|--|------------|-------------|
| <b>Local reactions for 1-2 days</b>                    | 11%-59%    | 4%-48%      |
| <b>Fever <math>\geq 100^{\circ}\text{F}</math></b>     | 5%         | 3%          |
| <b>Systemic reactions (headache, malaise, fatigue)</b> | 4-62%      | 3-60%       |

**VIII. OTHER CONSIDERATIONS**

- A. MCV4 and MPSV4 meningococcal vaccines will stimulate protection only against infections caused by organisms from serogroups A, C, Y and W-135 meningococci. They are not protective against serogroup B meningococci, the most prevalent group in Oregon.
- B. If MCV4 or MPSV4 are used in persons receiving immunosuppressive therapy, the expected immune response may not be obtained.
- C. ACIP expects that MCV4 will provide longer protection than MPSV4; however, studies are needed to confirm this assumption.
- D. Patients with HIV are likely at increased risk for meningococcal disease, although not to the extent that they are at risk for invasive *S. pneumoniae* infection. Although the efficacy of MCV4 among HIV-infected patients is unknown, they may elect vaccination.
- E. Both MCV4 and MPSV4 can be used for outbreak control, although MCV4 is preferred if the population targeted includes ages & serogroups for which MCV4 is licensed.
- F. Antimicrobial chemoprophylaxis: Antimicrobial postexposure chemoprophylaxis of close contacts of sporadic cases of meningococcal disease is the primary means for prevention of

meningococcal disease in the United States. Close contacts include

- a) household members,
- b) daycare-center contacts, and
- c) anyone directly exposed to the patient’s oral secretions.

Contacts of cases should be referred to their primary healthcare provider and local health department for treatment and follow-up. See the *Investigative Guideline* for meningococcal disease for more details:

[www.oregon.gov/dhs/ph/acd/reporting/guideln/mening.pdf](http://www.oregon.gov/dhs/ph/acd/reporting/guideln/mening.pdf)

- G. Protective levels of antibodies are usually achieved within 7-10 days after vaccination.
- H. For someone with a history of fainting with injections, a 15-minute observational period is recommended post immunization.

## IX. ADVERSE EVENT REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: <http://vaers.hhs.gov>. In addition, a copy of the completed VAERS form should be sent to the patient’s primary provider, per ORS 855-041-0510

## X. REFERENCES

1. Revised Recommendations of ACIP to vaccinate all persons aged 11–18 years with meningococcal conjugate vaccine. MMWR 2007; 56(31); 794–5.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5631a3.htm>

2. Recommendation from the ACIP for use of quadrivalent meningococcal conjugate vaccine (MCV4) in children aged 2–10 years at increased risk for invasive meningococcal disease. MMWR 2007; 56(48); 1265–6.

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5648a4.htm?s\\_cid=m5648a4\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5648a4.htm?s_cid=m5648a4_e)

3. Guillain-Barré Syndrome Among Recipients of Menactra® meningococcal Conjugate Vaccine — United States, June–July 2005, MMWR Vol. 54, Dispatch, 10/6/05;  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm54d1006a1.htm>
4. Prevention and control of meningococcal disease: recommendations of the ACIP. MMWR 2005; 54(RR-7); Revised 2007:  
<http://www.cdc.gov/vaccines/ed/vpd2007/downloads/slides/Mening10br.ppt#336,1,Slide 1>
5. Meningococcal Disease. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases* (“Pink Book”). Atkinson W, Hamborsky J, Wolfe S, eds. 10th ed. Washington, DC: Public Health Foundation, 2008:271-282. Available at  
<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/mening-508.pdf>
6. Menactra™ package insert at:  
<http://www.fda.gov/cber/label/menactraLB.pdf>
7. Menomune® package insert at:  
<http://www.fda.gov/cber/label/menomuneLB.pdf>
8. <http://www.immunize.org/laws/#menin>

Electronic copy of this protocol available at:

<http://www.oregon.gov/dhs/ph/imm/provider/pharmpro.shtml>

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