
Meningococcal B Vaccine (Bexsero[®]): Q&A for health care providers

This questions and answers sheet for health care professionals provides basic information only. It is not intended to provide or take the place of medical advice, diagnosis or treatment

Effective December 2014, Ontario has introduced the multicomponent meningococcal B vaccine (4CMenB or Bexsero[®]) as part of its publicly funded high risk meningococcal immunization program for individuals 2 months to 17 years of age with specific high risk conditions.

What is invasive meningococcal disease (IMD)?

IMD is caused by bacteria known as *Neisseria meningitidis*. Among the different strains of meningococcal bacteria, five (A, B, C, Y and W-135) cause the majority of cases of meningococcal disease. Many people (10% of the population) carry the bacteria at the back of their throat or nose without feeling sick. In rare instances, the bacteria overcome the body's natural defenses and cause serious diseases, including meningitis (infection of the lining of the brain and spinal cord) and septicemia (widespread infection involving the blood and multiple organs). Meningococcal disease is fatal in 8-15% of cases and 11 to 19% of survivors will suffer some form of permanent disability, such as hearing loss, neurological damage or limb loss.

Within Canada, incidence of disease varies by age; however, infants under one year of age are at highest risk of IMD caused by serogroup B disease.

The symptoms of meningococcal disease can vary widely, but can include sudden onset of high fever, severe headache, vomiting, stiff neck and a rash. Sensitivity to light, sleepiness, confusion and, in severe cases, coma may also occur. Meningococcus bacteria are spread by direct contact with respiratory and oral secretions or, in other words, contact with saliva with an infected person. To prevent the spread of meningococcal disease, objects that have come in contact with another person's mouth should not be shared. Furthermore, good hand hygiene and the use of sleeves, the shoulder, or tissues to cover coughs or sneezes is important to practice consistently.

What is the epidemiology of IMD in Ontario?

According to Ontario's integrated Public Health Information System (iPHIS) and records from the Public Health Ontario Laboratories (PHOL), there were 793 IMD cases reported in Ontario between 2000 and 2012. The annual incidence rate ranged from 0.94 cases per 100,000 population in 2001 to 0.26 cases per 100,000 population in 2012. The incidence of IMD attributable to serogroup C declined

significantly over the years, declining from 0.30 cases per 100,000 population in 2001 to 0.01 cases per 100,000 population in 2012. A decrease in incidence of serogroup Y and W-135 have also been observed. Conversely, no evident decline in serogroup B incidence has been observed.

Serogroup B was the most frequently reported IMD serogroup in 2012, accounting for approximately 77% of IMD cases reported in Ontario that year. Twenty-two confirmed serogroup B IMD cases were reported for an overall rate of 0.16 per 100,000 population. Disease incidence was highest among infants less than one year of age, with a smaller peak among children 1-4 and adolescents in the 15-19 year age group. Overall, 64% of cases reported in 2012 were female.

About the publicly funded Meningococcal B Vaccine (Bexsero®)

In December 2013, Health Canada approved Bexsero®, a novel multicomponent meningococcal B vaccine (4CMenB), manufactured by Novartis. Bexsero® protects against meningococcal serogroup B disease, and has been authorized for use in individuals 2 months through 17 years of age.

For more information about the vaccine, refer to the vaccine product monograph available at: www.bexsero.ca/en/hcp/resources.shtml

Who is eligible to receive the publicly funded 4CMenB vaccine and when should they receive it?

Starting in December 2014, the ministry is offering the 4CMenB to individuals with high risk conditions from 2 months through 17 years of age with the following conditions:

- a. Individuals with functional or anatomic asplenia
- b. Individuals with complement, properdin, factor D or primary antibody deficiencies
- c. Cochlear implant recipients (pre/post implant)
- d. Individuals with acquired complement deficiencies (e.g., receiving eculizumab)
- e. Individuals with HIV

The vaccine is also publicly funded for close contacts of a case of serogroup B IMD that meets the public health criteria for chemoprophylaxis as well as for individuals at risk during IMD outbreaks caused by *N. meningitis* serogroup B or the emergence of hyperendemic and/or hypervirulent *N. meningitis* strains that are predicted to be susceptible to vaccine.

The recommended schedules are summarized below:

Age at series initiation	Number of doses	Schedule
2 to 5 months	3+1	1 st dose 2 nd dose, 2 months after 1 st dose 3 rd dose, 2 months after 2 nd dose 4 th dose, 2 months after 3 rd and at age ≥12 months
6 to 11 months	3	1 st dose 2 nd dose, 2 months after 1 st dose 3 rd dose, 2 months after 2 nd dose and at age ≥12 months
12 months to 10 years	2	1 st dose 2 nd dose, 2 months after 1 st dose

Age at series initiation	Number of doses	Schedule
11 to 17 years	2	1 st dose 2 nd dose, 1 month after 1 st dose

Two to four doses are required for individuals, depending on the age at first dose. For more details about dosing, refer to the product monograph.

Why has the ministry introduced a High Risk 4CMenB Immunization Program?

In order to optimize protection against meningococcal serogroup B disease, Ontario's high risk meningococcal immunization program has been updated to publicly fund the 4CMenB vaccine for high risk individuals between the ages of 2 months to 17 years. These changes align with current scientific recommendations from the National Advisory Committee on Immunization, within the age indications approved for use in Canada.

Can the 4CMenB vaccine be given simultaneously with other vaccines?

The 4CMenB can generally be given simultaneously with other infant vaccines, either monovalent or as combination vaccines: meningococcal conjugate C, diphtheria, tetanus, acellular pertussis, *Haemophilus influenzae* type b, inactivated polio, hepatitis B, heptavalent pneumococcal conjugate, measles, mumps, rubella and varicella.

Who should not receive the vaccine?

Individuals with a history of anaphylaxis after a previous dose of a 4CMenB vaccine and individuals with proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its container should not receive the vaccine.

Precautions should be taken for the following individuals who:

- are allergic to latex
- have a weakened immune system
- have a bleeding disorder (hemophilia or any other condition that may slow down blood clotting) or taking blood-thinning medications
- have a severe infection with a high temperature
- have an allergy to any component of the vaccine, including allergy to the antibiotic kanamycin
- are pregnant, breastfeeding, think they may be pregnant or are planning to have a baby .

What is the vaccine ordering process?

Order the 4CMenB vaccine for high risk individuals through your public health unit using localized order forms. Information about your public health unit can be found at:

<http://www.phdapps.health.gov.on.ca/PHULocator>.

How should the 4CMenB vaccine be stored?

In order to ensure that individuals receive optimal protection, the 4CMenB vaccine (like other vaccines) must be maintained at a temperature between +2°C to +8°C from the time of manufacture until the vaccine is administered to individuals. This temperature *must* be monitored and maintained at all times.

For additional information on provincial vaccine storage and handling requirements please consult the Vaccine Storage and Handling Guidelines, available at:

http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/guidance/guide_vaccine_storage.pdf

Is the 4CMenB vaccine safe and effective?

Yes, the 4CMenB vaccine is very safe and effective. Vaccine safety is a priority for the ministry. All publicly funded vaccines have to be tested to make sure they are both safe and effective. Vaccine safety is continually monitored by public health.

In infants and children (up to 10 years of age), common side effects of the vaccine tend to be mild and may include fever, loss of appetite, tenderness or discomfort at the injection site, skin rash, sleepiness, feeling irritable, unusual crying, vomiting and diarrhea. Other side effects in individuals 11 years of age and older may include pain at the injection site, painful muscles and joints, nausea, generally feeling unwell and headache. Severe reactions are rare.

Fever is a common side-effect of this vaccine in young children. The National Advisory Committee on Immunization (NACI) recommends considering routine prophylactic administration of acetaminophen and/or separating 4CMenB vaccine administration from other routine immunizations for preventing fever in infants and children up to three years of age.

If your patient experiences an adverse event following immunization (AEFI), please complete the AEFI steps below (next section) and send it to your local public health unit. You should always discuss the benefits and risks of any vaccine with your patient.

What should be done for adverse events following immunization (AEFIs)?

Provincial reporting of AEFI or post-marketing surveillance is an important component of the overall safety assessment of any vaccine. Under section 38 of the ***Health Protection and Promotion Act, R.S.O. 1990***, Ontario physicians, nurses, pharmacists and other health care providers (as listed under the section) are required to inform the person who consents to immunization of the importance of immediately reporting to a physician or a registered nurse in the extended class (nurse practitioner) of any reaction that may be a reportable event. Local public health units should subsequently be notified of the adverse event. The AEFI reporting form can be found on the Public Health Ontario (PHO) website along with a questions and answers fact sheet, available at:

www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/Pages/Immunization-Resources.aspx. Please send the completed form to your local public health unit.

This information is monitored and reviewed on an ongoing basis by PHO and reported to the Public Health Agency of Canada (PHAC) to support national vaccine safety surveillance. Health care

providers are required to report AEFIs to their local public health unit. A list of public health units in Ontario is available at www.health.gov.on.ca/en/common/system/services/phu/locations.aspx

Who can I contact for more information?

- Further information, including Ontario's publicly funded immunization schedule, is available on the Ministry of Health and Long-Term Care's website for health care professionals at: www.health.gov.on.ca/en/pro/programs/immunization.
- If you have further questions, please contact your local public health unit. To find your local public health unit, visit: www.phdapps.health.gov.on.ca/PHULocator.
- Immunization information is available at: www.ontario.ca/vaccines.