



CHOOSE TO

# VACCINATED

Vaccinate against meningococcal disease caused by MenB (*Neisseria meningitidis* group B strains) with **BEXSERO**

BEXSERO multicomponent meningococcal B vaccine (recombinant, adsorbed) is a vaccine for the prevention of meningococcal disease caused by *Neisseria meningitidis* group B bacteria in individuals from 2 months through 17 years of age. BEXSERO is not expected to provide protection against all circulating meningococcal serogroup B strains and does not offer protection against strains A, C, Y, and W-135. As with any vaccine, BEXSERO may not fully protect all of those who are vaccinated. BEXSERO does not treat or reduce the consequences of meningococcal meningitis, including meningitis, sepsis, and death.

**Ask your doctor about vaccination for MenB\*.**



**BEXSERO**

Multicomponent Meningococcal B Vaccine  
(recombinant, adsorbed)

**B vaccinated.**

\* MenB is meningococcal disease caused by *Neisseria meningitidis* group B strains.

# UNDERSTANDING meningococcal disease

caused by *Neisseria meningitidis* group B strains

## What is meningococcal disease?

Meningococcal disease is a rare but potentially serious infection caused by different **strains** of ***Neisseria meningitidis*** also known as **meningococcus bacteria**.

Meningococcus bacteria includes *Neisseria meningitidis* group B strains.

The most common forms of meningococcal disease are:

**Meningococcal meningitis** — an infection of the lining of the brain and spinal cord and;

**Septicemia** — an infection of the bloodstream.

## What are the symptoms?

Symptoms begin mildly like a cold or flu: **fever, headache, aches and pains** in joints and muscles. These can progress rapidly into much more severe effects.

Although most people fully recover, up to **1 in 10 patients die**, typically within **24 to 48 hours** after the onset of symptoms. Of those who recover, up to **1 in 5 experience serious complications**.



Meningococcal disease starts quickly and may progress rapidly to cause serious, possibly life-threatening infections.

# About meningococcal disease caused by MenB (*Neisseria meningitidis* group B strains)

## What causes meningococcal disease?

Among the different groups of meningococcal bacteria, five—A, B, C, W-135 and Y—cause the most cases of meningococcal disease.

In Canada, the number of cases caused by each group of bacteria varies from year to year. From 2004 to 2007, there was an increase of MenB\*.

In fact, in 2011, MenB\* was the most common form of meningococcal disease in Canadians.

In Canada, between 2007 and 2011, the average annual incidence (per 100,000 population) of MenB\* was highest in:

- **Infants** under 1 year of age, followed by
- **Children** 1 to 4 years of age, and
- **Adolescents** aged 15 to 19 years.†

## How can you help protect your child against meningococcal disease caused by *Neisseria meningitidis* group B strains?

Prevention is the best strategy for combating any infectious disease.

## Ask your doctor about vaccination for MenB\*.

BEXSERO is not expected to provide protection against all circulating meningococcal serogroup B strains and does not offer protection against strains A, C, Y, and W-135. As with any vaccine, BEXSERO may not fully protect all of those who are vaccinated.

\* MenB is meningococcal disease caused by *Neisseria meningitidis* group B strains.

† BEXSERO is indicated for children 2 months to 17 years of age.

# ABOUT **BEXSERO**

The first and only vaccine to help protect against meningococcal disease caused by MenB (*Neisseria meningitidis* group B strains) in children 2 months through 17 years of age.

## **What is BEXSERO?**

BEXSERO is a vaccine for the prevention of meningococcal disease caused by *Neisseria meningitidis* group B strains.

**MenB\*** may lead to serious, and sometimes life-threatening, infections such as meningitis (infection of the lining of the brain and spinal cord) and sepsis (blood poisoning).

## **How does it work?**





The vaccine stimulates the body's own immune system to produce *antibodies*.

These antibodies kill *Neisseria meningitidis* group B bacteria that cause meningococcal disease. If a vaccinated person is infected by these bacteria, their immune system can be prepared to respond and help protect against infection and disease.

BEXSERO does not treat or reduce the consequences of meningococcal meningitis, including meningitis, sepsis, and death.

\* MenB is meningococcal disease caused by *Neisseria meningitidis* group B strains.

## RECOMMENDED VACCINATION SCHEDULE

Age group 	Primary doses 	Interval between primary doses 	Booster dose 
<b>Infants</b> 2 to 5 months of age	3 doses	$\geq 1$ month	<b>1 dose</b> required in the second year of life between 12 and 23 months of age.  This dose should be given early in the second year of life, whenever possible
<b>Infants</b> 6 to 11 months of age (unvaccinated)	2 doses	$\geq 2$ months	<b>1 dose</b> required in the second year of life, after an interval of at least 2 months from the last dose. The need for further doses has not been established.
<b>Children</b> 12 months up to 10 years of age*	2 doses	$\geq 2$ months	The need for further doses has not been established.
<b>Adolescents</b> 11 to 17 years of age	2 doses	$\geq 1$ month	The need for further doses has not been established.

\* The 12 months to 10 years of age population includes unvaccinated children aged 12 months through 23 months.

**Make sure that your child gets the full vaccination series. This allows your child to get the full benefits of BEXSERO.**

### What if a dose is missed?

If you forget to go back to the doctor, pharmacist, or nurse at the scheduled time, ask your respective healthcare professional for advice.

### Where is BEXSERO administered?

BEXSERO will be injected into your child's arm or leg muscle depending on age.

Talk to your doctor, pharmacist, or nurse for further information.

## Potential side effects and what to do about them.

Like all vaccines, BEXSERO may cause side effects.

When BEXSERO is administered, the most frequent side effects (more than 1 in 10 people) your child may get are pain/tenderness at the injection site, redness at the injection site, swelling at the injection site, hardness at the injection site.

### Infants and children (up to 10 years of age)

**Very common** (may affect more than 1 in 10 people)

- Fever ( $\geq 38^{\circ}\text{C}$ )
- Loss of appetite
- Tenderness or discomfort at the injection site (including severe injection site tenderness resulting in crying when injected limb is moved)
- Skin rash (uncommon after booster)
- Sleepiness
- Feeling irritable
- Unusual crying
- Vomiting
- Diarrhea

Your doctor, pharmacist or nurse may ask you to give your child medicines that help lower fever at the time, and after, BEXSERO has been administered. This may help reduce some of the side effects of BEXSERO.

## Individuals from 11 years of age and older

**Very common** (may affect more than 1 in 10 people)

- Pain at the injection site resulting in inability to perform normal daily activity
- Painful muscles and joints
- Nausea
- Generally feeling unwell
- Headache

If any of the noted side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse immediately.

### Side effects that have been reported during marketed use include:

Allergic reactions that may include severe swelling of the lips, mouth, throat (which may cause difficulty in swallowing), difficulty breathing with wheezing or coughing, rash, loss of consciousness and very low blood pressure; collapse (sudden onset of muscle floppiness), less responsive than usual or lack of awareness, and paleness or bluish skin discolouration in young children; feeling faint or fainting; fever (adolescents from 11 years of age and adults); blisters at or around the injection site.

If any of the noted side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist, or nurse immediately.

*This is not a complete list of side effects. For any unexpected effects while taking BEXSERO, contact your doctor, pharmacist, or nurse.*



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Multicomponent Meningococcal B Vaccine  
(recombinant, adsorbed)

**B vaccinated.**

# WARNINGS AND **PRECAUTIONS**

BEFORE your child receives BEXSERO, talk to your doctor, pharmacist, or nurse if:

- They have a severe infection with a high temperature. If so, then vaccination will be postponed. The presence of a minor infection, such as a cold, should not require postponement of the vaccination.
- They are pregnant or breast feeding, or think they may be pregnant or are planning to have a baby.
- They have hemophilia or any other condition that may slow down the clotting of the blood, such as treatment with blood thinners (anticoagulants).
- They were born prematurely (before or at 28 weeks of pregnancy), particularly with breathing difficulties. Stopping breathing or irregular breathing for a short time may be more common in the first three days following vaccination in these babies and they may need special monitoring.
- They have an allergy to the antibiotic kanamycin or to latex. If present, the kanamycin level in the vaccine is low.

Fainting, feeling faint or other stress-related reactions can occur as a response to any needle injection. Tell your doctor, pharmacist, or nurse if they have ever experienced this kind of reaction.

If your child has a weakened immune system, it is possible that the effectiveness of BEXSERO is reduced.

As with any vaccine, BEXSERO may not fully protect all of those who are vaccinated. Additionally, BEXSERO is not expected to provide protection against all circulating meningococcal serogroup B strains and doesn't protect against strains A, C, Y and W-135.



## **When BEXSERO should not be used.**

BEXSERO should not be used if your child is allergic (hypersensitive) to the active substances or any of the other ingredients of BEXSERO.

## **Important information about BEXSERO**

You are advised to discuss the advantages and disadvantages of BEXSERO with your healthcare professional before receiving the vaccine.

**To learn more about BEXSERO,  
visit [bexsero.ca](http://bexsero.ca).**

**Reporting an adverse event:** Your own healthcare professional is the best source of information regarding your health. If you need to report an adverse event, please call 1-800-387-7374.

# WHERE CAN I GET **BEXSERO?**

BEXSERO is administered at doctors' offices and in vaccination clinics.

## **Is the cost of BEXSERO covered?**

The cost of BEXSERO may be covered by your private insurance. Contact your insurance provider and give the DIN (drug identification number) here to find out:

**BEXSERO DIN: 02417030**



# YOUR CHILD’S VACCINATION SCHEDULE

- Step 1:** Talk to your doctor about vaccinating your child with BEXSERO.
- Step 2:** Make an appointment for your child’s first dose of BEXSERO and note it below under “Date”.
- Step 3:** Bring this booklet with you to your child’s first dose so your doctor, pharmacist, or nurse can write down the dates and times of the following appointments.

## INFANTS UNDER 1 YEAR OF AGE

	Date	Time	Location
Dose 1			
Dose 2			
Dose 3			
Dose 4 (Only required for infants aged 2 to 5 months)			

## CHILDREN 1 TO 17 YEARS OF AGE

	Date	Time	Location
Dose 1			
Dose 2			

If the date has not been set for a dose, use the “Date” column to note when you are expected to call to schedule the appointment.

**Don’t forget!**  
Bring your child’s vaccination booklet to each appointment to keep it up to date.

## Notes



**BEXSERO**

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HELP PROTECT YOUR  
CHILD AGAINST  
MENINGOCOCCAL  
DISEASE CAUSED BY **MenB**  
(*Neisseria meningitidis*  
group B strains)



ASK YOUR DOCTOR ABOUT VACCINATION FOR **MenB\***

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**Visit [bexsero.ca](http://bexsero.ca) for more information**



MEMBER OF  
INNOVATIVE MEDICINES CANADA

\* MenB is meningococcal disease caused by *Neisseria meningitidis* group B strains.

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07/17