CONSUMER INFORMATION

BEXSERO®

Multicomponent Meningococcal B Vaccine (recombinant, adsorbed)

This leaflet is Part III of a three-part "Product Monograph" published when BEXSERO was approved for sale in Canada and designed specifically for consumers. This leaflet is a summary and will not tell you everything about BEXSERO. Contact your doctor/pharmacist/nurse if you have any questions about the vaccine.

ABOUT THIS VACCINE

What the vaccine is used for:

BEXSERO is a vaccine for the prevention of Meningococcal disease caused by the Neisseria meningitidis group B bacteria (germs). These germs can cause serious, and sometimes life-threatening, infections such as meningitis (infection of the lining of the brain and spinal cord) and sepsis (blood poisoning). BEXSERO is given to individuals from 2 months through 17 years of age.

What it does:

The vaccine works by specifically stimulating the immune system of the vaccinated person, causing the production of substances in the blood called antibodies. The antibodies kill the germ that causes meningococcal disease, N. meningitidis. If a vaccinated person is infected by N. meningitidis, their immune system is usually ready to destroy it.

When it should not be used:

If you or your child are allergic (hypersensitive) to the active substances or any of the other ingredients of BEXSERO

What the medicinal ingredients are:

The active substances are:
50 μg of recombinant Neisseria meningitidis group B NHBA fusion protein
50 μg of recombinant Neisseria meningitidis group B NadA protein
50 μg of recombinant Neisseria meningitidis group B fHbp fusion protein
25 μg of Outer Membrane Vesicles Neisseria meningitidis group B strain NZ98/254

Antigens are adsorbed on aluminum hydroxide (0.5 mg aluminum).

What the important nonmedicinal ingredients are:

Sodium chloride, histidine, sucrose, water for injections.

For a full listing of non-medicinal ingredients, see Part I of the Product Monograph.

What dosage forms are available?

Each dose of 0.5 mL is a suspension for intramuscular injection provided in a prefilled glass (Type I) syringe. Syringes are available in packages containing either one or ten syringes, supplied with or without needles.

WARNINGS AND PRECAUTIONS

BEFORE you or your child receive BEXSERO, talk to your doctor/pharmacist/nurse if:

- you or your child have a severe infection with a high temperature. If this is the case, then vaccination will be postponed. The presence of a minor infection, such as a cold, should not require postponement of the vaccination, but talk to your doctor/pharmacist/nurse first.
- you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor/pharmacist/nurse for advice before BEXSERO is given.
- you have hemophilia or any other condition that may slow down the clotting of your blood, such as treatment with blood thinners (anticoagulants).
- you or your child have an allergy to the antibiotic kanamycin. If present, the kanamycin level in the vaccine is low. If you or your child may have allergy to kanamycin, talk to your doctor/pharmacist/nurse first.

Tell your doctor/pharmacist/nurse if you know that you or your child is allergic to latex. The tip cap of the syringe may contain natural rubber latex. Although the risk for developing allergic reactions is very small, your doctor/pharmacist/nurse should consider the benefit-risk prior to administering this vaccine to subjects with known history of hypersensitivity to latex.

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

There are no data on the use of BEXSERO in patients with chronic medical conditions or with weakened immunity. If you or your child have weakened immunity (for example, due to the use of immunosuppressive medications, or HIV infection, or hereditary defects of the body’s natural defense 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.

BEXSERO is not expected to provide protection against all circulating meningococcal serogroup B strains.

BEXSERO has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned...
under section “Side effects and what to do about them” may temporarily affect the ability to drive or use machines.

INTERACTIONS WITH THIS VACCINE

Tell your doctor/pharmacist/nurse if you or your child are taking, have recently taken, or might take any other medicines, or have recently received any other vaccine. BEXSERO can be given at the same time as any of the following vaccine antigens, either as monovalent or as combination vaccines: diphtheria, tetanus, acellular pertussis (whooping cough), Haemophilus influenzae type b, inactivated polio, hepatitis B, heptavalent pneumococcal conjugate, measles, mumps, rubella, and chickenpox. Talk to your doctor/pharmacist/nurse for further information.

When BEXSERO is given at the same time as any other vaccine, the vaccines must be given at separate sites.

PROPER USE OF THIS VACCINE

Usual dose:
Your doctor/pharmacist/nurse will inject the recommended dose (0.5 mL) of the vaccine into your or your child's arm or leg muscle. BEXSERO must not be mixed with any other vaccine or medicinal products in the same syringe.

Infants aged 2 months through 5 months
Your child should receive an initial course of three injections of the vaccine followed by a fourth dose. The interval between vaccinations should be at least 1 month. A fourth vaccination is required in the second year of life between 12 and 23 months of age. It is preferred this dose be given early in the second year of life, whenever possible.

Unvaccinated infants aged 6 months through 11 months
Infants aged 6 through 11 months should receive two injections, given at least 2 months apart. A third injection is required in the second year of life, after an interval of at least 2 months from the last dose. The need for further injections has not been established.

Unvaccinated children aged 12 months through 23 months
Children aged 12 through 23 months should receive two injections, given at least 2 months apart. The need for further injections has not been established.

Children aged 2 years through 10 years
Children aged 2 through 10 years should receive two injections, given at least 2 months apart. The need for a third injection has not been established.

Individuals aged 11 years through 17 years
Individuals aged 11 through 17 years of age should receive two injections. The interval between each injection should be at least 1 month. The need for a third injection has not been established. Make sure that you or your child gets all doses. This allows you or your child to get the full benefits of BEXSERO.

Missed Dose:
If you forget to go back to the doctor/pharmacist/nurse at the scheduled time ask the doctor/pharmacist/nurse for advice.

If you have any further questions on the use of BEXSERO, ask your doctor/pharmacist/nurse.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all vaccines, BEXSERO can cause side effects, although not everybody gets them. When BEXSERO is given to you or your child, the very common side effects (may affect more than 1 in 10 people) that you or your child may get (reported in all age groups) are:
- pain/tenderness at the injection site
- redness of the skin at the injection site, swelling of the skin at the injection site, hardness of the skin at the injection site

The following side effects may also occur after receiving this vaccine.

Infants and children (up to 10 years of age)
Very common (these may affect more than 1 in 10 people)
- fever (≥38°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

Uncommon (these may affect up to 1 in 100 people)
- high fever (≥40°C)
- seizures (including febrile seizures)
- vomiting (after booster)
- dry skin, itchy rash, skin rash
- paleness (rare after booster)

Rare (these may affect up to 1 in 1,000 people)
- Kawasaki disease which may include symptoms such as fever that lasts for more than five days, associated with a skin rash on the trunk of the body, and sometimes followed by a peeling of the skin on the hands and fingers, swollen glands in the neck, red eyes, lips, throat and tongue.

Individuals from 11 years of age and older
Very common (these 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/nurse immediately.

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

**HOW TO STORE IT**

Store in a refrigerator at 2°C to 8°C.
Do not freeze. Do not use vaccine that may have been frozen.
Protect from light.
Do not use BEXSERO after the expiry date.
Keep out of reach of children.

**REPORTING SUSPECTED SIDE EFFECTS**

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

**For health care professionals:**
If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local health unit in your province/territory.

**For the General Public:**
Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada:

By toll-free telephone: 866-844-0018
By toll-free fax: 866-844-5931
Email: caefi@phac-aspc.gc.ca

Mail:
The Public Health Agency of Canada
Vaccine Safety Section
130 Colonnade Road, A/L 6502A
Ottawa, ON K1A 0K9

*NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.*

This document plus the full product monograph, prepared for health professionals can be found at: http://www.novartis.ca or by contacting the sponsor, Novartis Vaccines and Diagnostics Inc., at 1-800-363-8883

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