PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

BEXSERO
Multicomponent Meningococcal B Vaccine (recombinant, adsorbed)

Read this carefully before you are given **BEXSERO** and each time you are given this vaccine. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about any medical condition and treatment, and ask if there is any new information about **BEXSERO**.

What is BEXSERO 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 invasive meningococcal group B disease (also known as Meningitis B or MenB) which can 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).

BEXSERO is given to individuals from 2 months through 25 years of age.

How does BEXSERO work?

BEXSERO 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.

BEXSERO has been shown to reduce new cases of Meningitis B (MenB) in infants by 75% in an UK national immunization program between 2015-2018.

What are the ingredients in BEXSERO?

Medicinal ingredients:
50 mcg of recombinant *Neisseria meningitidis* group B NHBA fusion protein
50 mcg of recombinant *Neisseria meningitidis* group B NadA protein
50 mcg of recombinant *Neisseria meningitidis* group B fHbp fusion protein
25 mcg of Outer Membrane Vesicles *Neisseria meningitidis* group B strain NZ98/254

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

(mcg = micrograms)

Non-medicinal ingredients: Aluminium hydroxide, histidine, sodium chloride, sucrose, water for injections. Residue from the manufacturing process: kanamycin.

BEXSERO comes in the following dosage forms:

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.

Do not use BEXSERO if:

- You or your child are allergic (hypersensitive) to the active substances or any of the other ingredients of BEXSERO.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BEXSERO. Talk about any health conditions or problems you may have, including 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 healthcare professional first.
- you or your child receive treatment that blocks the part of the immune system known as complement activation, such as eculizumab. Even if you have been vaccinated with BEXSERO you remain at increased risk of disease caused by the *Neisseria meningitidis* group B bacteria.
- you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before BEXSERO is given.
- you or your child have hemophilia or any other condition that may slow down the clotting of your blood, such as treatment with blood thinners (anticoagulants).
- your child was 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.
- 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 healthcare professional first.
- 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 healthcare professional should consider the benefit-risk prior to administering this vaccine to individuals with known history of hypersensitivity to latex.

Other warnings you should know about:

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

Your healthcare professional 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 limited 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 does not affect your 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.

Use of BEXSERO with other vaccine and medicines:

Tell your healthcare professional 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, chickenpox, and meningococcal groups A, C, W, Y conjugate. Talk to your healthcare professional for further information.

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

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take BEXSERO:

Usual dose:

Your healthcare professional 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 to 5 months at the time of first dose

Your child should receive an initial course of two or three injections of the vaccine followed by an additional injection (booster).

The interval between vaccinations should be at least 2 months if two initial doses are given or at least 1 month if three initial doses are given. A booster will be given in the second year of life after an interval of at least 6 months from the last injection of the initial course.

Infants aged 6 months to 11 months of age at the time of first dose

Your child should receive two injections of the vaccine, given at least 2 months apart. A booster will be given in the second year of life, after an interval of at least 2 months from the last dose.

Children aged 12 months to 23 months at the time of first dose

Your child should receive two injections of the vaccine, given at least 2 months apart. A booster will be given after an interval of 12 to 23 months from the second injection.

Children, Adolescents and Adults aged 2 through 25 years at the time of first dose

You or your child should receive two injections, given at least 1 month apart. An additional booster injection may be considered in individuals at continuous risk of exposure to meningococcal disease.

Make sure that you or your child gets all doses. This allows you or your child to get the full benefits of BEXSERO.

Overdose:

If you think you, or a person you are caring for, have taken too much BEXSERO, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to go back to the healthcare professional at the scheduled time ask the healthcare professional for advice. If you have any further questions on the use of BEXSERO, ask your healthcare professional.

What are possible side effects from using BEXSERO?

These are not all the possible side effects you may have when taking BEXSERO. If you experience any side effects not listed here, tell your healthcare professional.

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, redness, swelling, or hardness of the skin at the injection site.

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

Infants and children (2 months to 10 years of age)

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

- fever (≥38°C)
- loss of appetite

- tenderness 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 (uncommon after booster)
- diarrhea
- headache
- painful joints

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

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.

Adolescents and Adults (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

Side effects that have been reported during marketed use include:
- enlarged lymph nodes
- 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 discoloration in young children;
- feeling faint or fainting;
- fever (adolescents from 11 years of age and adults); injection site reactions like extensive swelling of the vaccinated limb, blisters at or around the injection site and hard lump at the injection site (which may persist for more than one month);
- skin rash (adolescents from 11 years of age and adults).

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

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional. Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and GSK cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php) and send it to your local Health Unit.

Storage:

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 and sight of children.

If you want more information about BEXSERO:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.gsk.ca, or by calling 1-800-387-7374.

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