BEXSERO®

Multicomponent Meningococcal group B vaccine (recombinant, adsorbed)

Consumer Medicine Information

What is in this leaflet

Read all of this leaflet carefully before you are vaccinated.

This leaflet answers some common questions about BEXSERO®.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. You can also download the most up-to-date leaflet from http://www.ebs.tga.gov.au/. Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you or your child having BEXSERO against the benefits they expect it will have for you.

If you have any concerns about this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet.
You may need to read it again.

What BEXSERO is used for

BEXSERO is a meningococcal group B vaccine.

BEXSERO is given to individuals from 2 months of age and older to help protect against disease caused by bacteria called Neisseria meningitidis group B. These bacteria can cause serious, and sometimes life-threatening, infections such as meningitis (inflammation of the covering of the brain and spinal cord) and sepsis (blood poisoning).

The vaccine works by specifically stimulating the body's natural defense system of the vaccinated person. This results in protection against this disease.

The use of this vaccine should be in accordance with the official recommendations.

Please note that BEXSERO can only protect you or your child from meningitis caused by Neisseria meningitidis group B.

BEXSERO is not expected to provide protection against all circulating meningococcal group B types.

How BEXSERO works

BEXSERO works by causing you or your child's body to produce its own protection (or antibodies), against the meningococcal group B bacteria. Your or your child's body usually takes a couple of weeks after vaccination to develop protection against Neisseria meningitidis group B.

If a vaccinated person comes into contact with Neisseria meningitidis group B, the body is usually able to destroy it. However, as with all vaccines, 100% protection cannot be guaranteed.

As with all vaccines, occasionally, individuals may react unfavourably to the vaccine.

The chance of a severe reaction from BEXSERO is very small, but the risks from not being vaccinated against meningococcal disease may be very serious.

BEXSERO should not be given to a person who has:

- allergy (hypersensitivity) to the active substances or any of the other ingredients of BEXSERO listed at the end of this leaflet. Signs of an allergic reaction may include:
  - shortness of breath, wheezing or difficulty breathing,
  - swelling of the face, lips, tongue or other parts of the body,
  - skin rash, itching or hives

In addition, BEXSERO should not be administered if:

- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

If you are not sure whether you or your child should have BEXSERO, talk to your doctor, nurse or pharmacist.

Before you or your child receives BEXSERO

Tell your doctor or pharmacist if you have/your child has allergies to:

- active substances or any of the other ingredients of BEXSERO
- the antibiotic kanamycin. If present, the kanamycin level in the vaccine is low
- latex. Although no natural rubber latex is detected in the syringe tip cap, the safe use of BEXSERO in latex-sensitive individuals has not been established.

Tell your doctor if in the past you or your child have/has reacted to any vaccination with any of the following:

- severe allergic reaction
- difficulty breathing
- swelling of the throat

Tell your doctor if you have/your child has 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 first.

If your child was born prematurely (before or at 28 weeks of pregnancy), particularly if they had breathing difficulties, please tell your doctor. 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.

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

Tell your doctor if you or your child have or have had any medical conditions especially the following:

- an immune deficiency condition. Little is known about the effectiveness of BEXSERO when administered to individuals with weakened immunity due to the use of immunosuppressive medications, or HIV infection, or hereditary defects of the body's natural defence system. It is possible the effectiveness of BEXSERO could be reduced in such individuals.

The safety and efficacy of BEXSERO in adults above 50 years of age have not been established. There are limited data on the use in patients with chronic medical conditions.

Tell your doctor if you are pregnant or intend to become pregnant soon.
Your doctor will discuss the possible risks and benefits of receiving BEXSERO vaccine during pregnancy. Your doctor may still recommend that you receive BEXSERO if you are at risk of exposure to meningococcal infection.

Tell your doctor if you are breastfeeding.
Your doctor will discuss the possible risks and benefits of receiving BEXSERO vaccine during breastfeeding.

Tell your doctor or pharmacist if you or your child are taking, or have recently taken, any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Having other vaccines

Tell your doctor if you or your child has had any vaccines recently.

BEXSERO may be given at the same time as other vaccinations.

When given at the same time as other vaccines, BEXSERO must be administered at a separate injection site. BEXSERO can be given at the same time as any of the following vaccines components:

diphtheria, tetanus, whooping cough (pertussis), Haemophilus influenzae type b, polio, hepatitis B, pneumococcus, measles, mumps, rubella, chickenpox and meningococcus C.

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

Your doctor or pharmacist may have more information on medicines and vaccines that require special precautions or should be avoided during vaccination with BEXSERO.

How BEXSERO is given

How it is given

BEXSERO is given as an injection, usually into your or your child's arm or leg muscle.

It is important to follow the instructions from your doctor or nurse so that you or your child completes the course of injections.

If you have any concerns about how this vaccine is to be given, talk to your doctor, nurse or pharmacist.

How much is given

The dose is 0.5 mL given by injection.

You or your child may be given more than one single dose of BEXSERO. Please talk to your doctor, nurse or pharmacist to get more information.

You should keep a record of your/ your child's vaccinations.

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child does not feel well after having BEXSERO.

Like all vaccines, BEXSERO can cause side effects, although not everybody gets them.

When BEXSERO is given to you or your child, the most common side effects that you may get are:

- pain at the injection site, redness at the injection site, swelling of skin at the injection site, hardness of skin at the injection site, generally feeling unwell, headache, fever (38°C or higher) and feeling irritable.

The following side effects may occur after receiving this vaccine:

Infants, toddlers and children (up to 10 years of age)

Very common:

- fever (38°C or higher), loss of appetite, tenderness or discomfort to touch at the injection site (including severe tenderness at injection site resulting in crying when injected limb was moved), redness of skin at the injection site, skin rash in toddlers (uncommon after booster), hardness of skin at the injection site, swelling of skin at the injection site, sleepiness, feeling irritable, unusual crying, vomiting (uncommon after booster), diarrhea, headache, painful joints.

Common:

- skin rash in infants and children aged 2 to 10 years, fever (39.5°C or higher).

  The incidence of fever may be decreased by the use of paracetamol. Before you or your child receives vaccination, ask your doctor about the risks of fever and how to treat it, including what to do if fever does not respond to initial treatment.

Uncommon:

- high fever (40°C or higher), seizures (including febrile seizures due to fever), dry skin, paleness (rare after booster).

Rare:

- Kawasaki disease which may include symptoms such as fever that lasts for more than five days, associated with a 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.
- Itchy rash, skin rash.

Adolescents (from 11 years of age) and Adults

Very common:

- pain at the injection site (including severe pain at injection site resulting in inability to perform normal daily activity), redness of skin at the injection site, swelling of skin at the injection site, hardness of skin at the injection site, painful muscles and joints, nausea, generally feeling unwell, headache.

Other side effects 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), 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)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

No studies on the effects on the ability to drive and use machines have been performed.

However, some of the side effects mentioned under section Side Effects may temporarily affect the ability to drive or use machines.

Ask your doctor or pharmacist to answer any questions you may have.

Storing BEXSERO

- **Keep BEXSERO away from light.**
- **Keep it in the refrigerator (between 2°C and 8°C).**
- **Do not freeze BEXSERO.**
- **Do not use BEXSERO after the expiry date which is stated on the carton.**
- **Keep out of the reach and sight of children.**

Medicines should not be disposed of in wastewater or household waste. Ask your doctor how to dispose of medicines that are out of date or no longer required. These measures will help to protect the environment.

Product description

What it looks like

BEXSERO is a white, opalescent liquid suspension for injection, supplied in a pre-filled syringe providing 1 dose of 0.5 ml.

Ingredients

The active ingredients are:

50 micrograms of Neisseria meningitidis Group B Neisseria Heparin Binding Antigen fusion protein (rbe); 50 micrograms of Neisseria meningitidis Group B Neisseria Adhesin A protein (rbe);

50 micrograms of Neisseria meningitidis Group B Factor H Binding Protein fusion protein

(rbe); 25 micrograms of Outer Membrane Vesicles from Neisseria meningitidis group B strain NZ98/254.

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

The other ingredients are: sodium chloride, histidine, sucrose and water for injections.

BEXSERO is supplied in packs of 1 or 10 syringes, supplied with or without needles.

Not all pack sizes may be marketed.

BEXSERO does not contain lactose, gluten, thiomersal (organic mercurials), tartrazine or any other azodyes.

Sponsor

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street
Abbotsford, Victoria, 3067

Australian Registration Numbers:

BEXSERO pre-filled syringe without needle (AUST R 190718)

BEXSERO pre-filled syringe with needle (AUST R 190719)

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Bexsero® is a registered trademark of the GSK group of companies

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