BEXSERO

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about receiving this vaccine, speak to your doctor, nurse or pharmacist.

1. Why am I receiving BEXSERO?

BEXSERO is a vaccine used for the immunisation of children from the age of 2 months and older, adolescents and adults to prevent disease caused by Neisseria meningitidis Group B. Neisseria meningitidis can cause meningitis, a very serious infection.

For more information, see Section 1. Why am I receiving BEXSERO? in the full CMI.

2. What should I know before I receive BEXSERO?

Do not receive BEXSERO if you have ever had an allergic reaction to BEXSERO or any of the ingredients listed at the end of the CMI.

Tell your doctor or nurse if you or your child have an allergy to kanamycin (an antibiotic), or allergy to any other vaccine or you have a very high fever or any other infection.

Talk to your doctor or nurse if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I receive BEXSERO? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BEXSERO and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I receive BEXSERO?

Your doctor or nurse will give you BEXSERO as an injection into your upper arm or for children into the upper thigh muscle.

More instructions can be found in Section 4. How do I receive BEXSERO? in the full CMI.

5. What should I know after receiving BEXSERO?

Things you should do	• Keep a record of your immunisation history
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how BEXSERO affects you
Looking after your vaccine	• BEXSERO will normally be stored at the doctor's surgery or in the pharmacy • If you need to store BEXSERO, keep it in the refrigerator between 2°C and 8°C. Do not freeze. Protect from light.

For more information, see Section 5. What should I know after receiving BEXSERO? in the full CMI.

6. Are there any side effects?

Side effects which have been reported following administration of BEXSERO include pain at the injection site, redness at the injection site, swelling of the skin at the injection site, hardness of skin at the injection

site, fever, a general feeling of being unwell, feeling irritable, unusual crying, loss of appetite, painful muscles and joints, headache, nausea, vomiting, diarrhoea, skin rashes and sleepiness.
Allergic reactions have also occurred following administration of BEXSERO. Allergy is rare and severe reactions will usually occur within the first few hours of vaccination. If this occurs go to the Emergency Department of the nearest hospital immediately.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

BEXSERO

Active ingredient(s): *multicomponent meningococcal group B vaccine (recombinant, adsorbed)*

Consumer Medicine Information (CMI)

This leaflet provides important information about receiving BEXSERO. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about receiving BEXSERO.**

Where to find information in this leaflet:

1. Why am I receiving BEXSERO?
2. What should I know before I receive BEXSERO?
3. What if I am taking other medicines?
4. How do I receive BEXSERO?
5. What should I know after receiving BEXSERO?
6. Are there any side effects?
7. Product details

1. Why am I receiving BEXSERO?

BEXSERO is a vaccine used for the active immunisation of individuals from 2 months of age and older to help prevent disease caused by Neisseria meningitidis serogroup B.

Neisseria meningitidis (meningococcal disease) can cause meningitis (inflammation of the spinal fluid and the tissues that surround the brain) or sepsis (blood poisoning). Meningococcal disease is an infectious disease that is spread from person to person through regular close contact through respiratory droplets. It is a very serious disease and is sometimes fatal. It may cause permanent physical and neurological damage.

BEXSERO can help to protect you or your child from meningococcal disease caused by Neisseria meningitidis group B. It is not expected to provide protection against all circulating meningococcal group B types or from meningococcal disease caused by different kinds of microbes.

BEXSERO works by causing your body to produce its own protection (antibodies) against meningococcal bacteria. Your body usually takes a few weeks after receiving the 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.

Sometimes 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.

2. What should I know before I receive BEXSERO?

Warnings

Do not receive BEXSERO if you or your child:

- are allergic to BEXSERO, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can receive this vaccine.

Check with your doctor or nurse if you or your child:

- are allergic to kanamycin, an antibiotic. If present, the level of kanamycin in the vaccine is low.
- have had an allergic reaction or become unwell after receiving any other vaccine.
- have a severe infection with a high temperature.
  In this case vaccination with BEXSERO may have to be delayed. A minor infection such as a cold should not be problem however talk to your doctor or nurse about this before being vaccinated.
- have any other medical conditions including any that involve your immune system
  Little is known about the effectiveness of BEXSERO when administered to individuals with weakened immunity due to the use of immunosuppressive medications or genetic disorders of the body's natural

defence system. It is possible the effectiveness of BEXSERO could be reduced in such individuals.

- take any medicines for any other condition
- have a condition that affects part of the immune system, such as certain complement deficiencies, or receive treatment (such as eculizumab) that blocks complement activation. Individuals could remain at risk of Neisseria meningitidis group B infection even after vaccination with BEXSERO.

If your child was born prematurely (before or at 28 weeks gestation), 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 3 days following vaccination in these babies and they may need special monitoring.

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

You may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

They will discuss with you the benefits and risks of receiving BEXSERO during pregnancy or whilst breastfeeding.

Fainting

Fainting can occur following, or even before, any needle injection. Tell the person giving you your injection if you or your child have ever fainted with a previous injection.

3. What if I am taking other medicines?

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

Some medicines may interfere with BEXSERO and affect how it works.
Tell your doctor or nurse if you or your child have had any vaccines recently.

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

Other vaccines must be injected into a different arm or leg from the site of the BEXSERO injection. These include any of the following vaccine components:

- diphtheria, tetanus, whooping cough (pertussis), Haemophilius influenzae type B, polio, hepatitis B, pneumococcal, measles, mumps, rubella, chickenpox and meningococcus A, C, W and Y.

Your doctor or nurse may ask you to give your child medicines that helps to lower fever (a common side effect). This will help to reduce some of the side effects of BEXSERO.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BEXSERO.

4. How do I receive BEXSERO?

How much is given

- Your doctor or nurse will give you BEXSERO as an injection
- The dose is 0.5 mL
- You or your child may be given more than one single dose of BEXSERO. Talk to your doctor or nurse for more information.

How it is given

- BEXSERO is injected into your upper arm or in children it can be given into the thigh muscle
- It should not be injected directly into a blood vessel or into or under the skin

If you or your child are given too much BEXSERO

If you think that you or your child have been given too much BEXSERO, you or your child may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know after receiving BEXSERO?

Things you should do

- keep a record of your/your child's vaccination history.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BEXSERO affects you.

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

Looking after your vaccine

- BEXSERO will usually be stored at the doctor's clinic or at the pharmacy.
- If you need to store BEXSERO it is important to keep it in the refrigerator between 2°C and 8°C.
- Keep BEXSERO in the carton to protect it from light.
- DO NOT FREEZE BEXSERO. FREEZING THIS MEDICINE WILL DESTROY THE VACCINE.

Follow the instructions in the carton on how to take care of your vaccine properly.
Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted vaccine

If you no longer need to use this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not receive this vaccine after the expiry date.

6. Are there any side effects?

All vaccines can have side effects. If you or your child do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Your doctor or nurse might ask you to remain for observation following your vaccination.

Less serious side effects

Less serious side effects	What to do
All age groups: Common: • General disorders and administration site conditions: pain at the injection site, redness at the injection site, swelling of the skin at the injection site, hardness of skin at the injection site • Nervous system disorders: headache • Musculoskeletal and connective tissue disorders: painful joints **Infants, toddlers and children up to 10 years of age:**	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
Very common: • General disorders and administration site conditions: fever (38°C or higher), tenderness at the injection site (including severe tenderness at the injection site resulting in crying when injected limb was moved), redness of skin at the injection site, hardness of skin at the injection site, swelling of skin at the injection site, feeling irritable • Metabolism and nutrition disorders: loss of appetite • Nervous system disorders: sleepiness, headache, unusual crying • Gastrointestinal disorders: vomiting (uncommon after booster), diarrhoea	

Less serious side effects	What to do
• Musculoskeletal and connective tissue disorders: painful joints Common: • Skin and subcutaneous tissue disorders: skin rash in infants and children aged 2 to 10 years • General disorders and administration site conditions: fever (39.5°C or higher) The incidence of fever may be decreased by the use of paracetamol. Before you or your child receives the 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.	

Adolescents from 11 years of age and adults: **Very common:** • **General disorders and administration site conditions: pain at the injection site (potentially severe which may lead to an inability to perform normal daily activity, redness of the skin at the injection site, swelling of the skin at the injection site, hardness of skin at the injection site, a general feeling of being unwell** • **Musculoskeletal and connective tissue disorders: painful muscles and joints** • **Gastrointestinal disorders: nausea** • **Nervous system disorders: headache**	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• Immune system disorders: allergic reaction Signs of an allergic reaction include: swelling of the limbs, face, eyes, inside of the nose, mouth or throat shortness of breath, breathing or swallowing difficulties hives, itching (especially of the hands or feet), reddening of the skin (especially around the ears) or severe skin reactions	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
unusual tiredness or weakness that is sudden and severe **Allergy to BEXSERO is rare. Severe reactions will usually occur within the first few hours of vaccination. If this occurs go to the Emergency Department of the nearest hospital immediately.** **Infants, toddlers and children up to 10 years of age:** Uncommon: • General disorders and administration site conditions: high fever (40°C or higher) • Nervous system disorders: seizures (including febrile seizures due to fever) • Skin and subcutaneous tissue disorders: dry skin, paleness (rare after booster)	

Serious side effects	What to do
Rare: • Skin and subcutaneous tissue disorders: itchy skin, skin rash • Vascular disorders: Kawasaki disease – symptoms may include fever that lasts more than 5 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, tongue	

Side effects reported during marketed use include:

- Blood and lymphatic system disorders: enlarged lymph nodes
- Immune system disorders: allergic reactions
- Nervous system disorders: collapse, sudden onset of muscle floppiness, less responsive than usual or a lack of awareness, feeling faint or fainting
- Skin and subcutaneous tissue disorders: paleness or bluish skin discolouration in young children, skin rash, fever (adolescents from 11 years of age and adults)

- General disorders and administration site conditions: 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)

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This vaccine is only available with a prescription.

What BEXSERO contains

Active ingredient **(main ingredient)**	Neisseria meningitidis Group B factor H binding protein fusion protein

	Neisseria meningitidis Group B Neisseria adhesin A protein Neisseria meningitidis Group B Neisseria heparin binding antigen fusion protein Neisseria meningitidis serogroup B outer membrane vesicles
Other ingredients **(inactive ingredients)**	aluminium hydroxide hydrate histidine sodium chloride sucrose water for injections

Do not receive this vaccine if you are allergic to any of these ingredients.

What BEXSERO looks like

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

BEXSERO pre-filled syringes without needle (AUST R 190718). Available in packs of 1 or 10.

Not all pack sizes may be marketed.

Who distributes BEXSERO

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford, VIC 3067

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