PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

Bexsero

suspension for injection in pre-filled syringe

Each dose (0.5 ml) contains:

four recombinant proteins from the *Neisseria meningitidis* group B bacteria:

Recombinant *Neisseria meningitidis* group B NHBA fusion protein	50 microgram
Recombinant *Neisseria meningitidis* group B NadA protein	50 microgram
Recombinant *Neisseria meningitidis* group B fHbp fusion protein	50 microgram
Outer membrane vesicles (OMV) from *Neisseria meningitidis* group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4	25 microgram

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – "Important information about some of the ingredients in the medicine" and section 6 – "Additional information".

Read the leaflet carefully in its entirety before you or your child are using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you or for your child. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Active immunization of individuals from 2 months of age and older against invasive meningococcal disease caused by *Neisseria meningitides* group B bacteria.

Therapeutic group:

Meningococcal group B vaccine

Bexsero contains four different components from the surface of the bacteria *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 immune system of the vaccinated person. This results in protection against the disease.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you or your child are sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in this medicine (listed in section 6).

Special warnings regarding use of the medicine

Before the treatment with Bexsero, tell the physician 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 or nurse first.
- you or your child have haemophilia or any other problem that may stop your blood from clotting properly, such as treatment with blood thinners (anticoagulants). Talk to your doctor or nurse 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 or your child have been vaccinated with Bexsero you or your child remain at increased risk of disease caused by the *Neisseria meningitidis* group B bacteria.

- your child was born prematurely (before or at 28 weeks of pregnancy), particularly if they had 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 an allergy to kanamycin, talk to your doctor or nurse first.

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 or nurse if you know that you or your child is allergic to latex. The tip cap of the syringe may contain natural rubber latex. The risk for developing an allergic reaction is very small, but your doctor or nurse needs to be aware of this allergy when deciding if you or your child can receive Bexsero.

There is no data on the use of Bexsero in adults above 50 years of age. 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 a hereditary defects of the body's natural immune system), it is possible that the effectiveness of Bexsero will be reduced.

As with any vaccine, Bexsero may not fully protect all of those who are vaccinated.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.

Tell your doctor or 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 components: diphtheria, tetanus, whooping cough (pertussis), *Haemophilus influenzae* type b, polio, hepatitis B, pneumococcus, measles, mumps, rubella, chickenpox, and meningococcus A, C, W, Y. Talk to your doctor or nurse for further information.

When given at the same time with other vaccines, Bexsero must be given at separate injection sites.
Your doctor or 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.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician for advice before you are given Bexsero. Your doctor may still recommend that you receive Bexsero if you are at risk of exposure to meningococcal infection.

Driving and using machines

Bexsero has no or negligible influence on the ability to drive and use machines.
However, some of the effects mentioned under section 4 ‘Side effects’ may temporarily affect the ability to drive or operate machines.

Important information about some of the ingredients in the medicine

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium-free’.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions.
Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the physician only.

Bexsero (0.5 ml) will be given to you or your child by a doctor or nurse. It will be injected into a muscle, usually the thigh for infants or the upper arm for children, adolescents, and adults.

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

The recommended dosage is usually:

Infants 2 months to 5 months of age 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 first injection should be given no earlier than 2 months of age.
- If three initial doses are given, the interval between injections should be at least 1 month.
- If two initial doses are given, the interval between injections should be at least 2 months.
- A booster will be given between 12 months and 15 months of age after an interval of at least 6 months from the last injection of the initial course. In case of delay, the booster should not be given later than 24 months of age.

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

Infants 6 months to 11 months of age should receive two injections of the vaccine followed by an additional injection (booster).

- The interval between each injection should be at least 2 months.
- A booster will be given in the second year of life after an interval of at least 2 months from the second injection.

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

Children 12 months to 23 months of age should receive two injections of the vaccine followed by an additional injection (booster).

- The interval between each injection should be at least 2 months.

- A booster will be given after an interval of 12 to 23 months from the second injection.

Children 2 years to 10 years of age at the time of first dose

Children 2 years to 10 years of age should receive two injections of the vaccine.

- The interval between each injection should be at least 1 month.

Your child may receive an additional injection (booster).

Adolescents and adults from 11 years of age at the time of first dose

Adolescents (from 11 years of age) and adults should receive two injections of the vaccine.

- The interval between each injection should be at least 1 month.

You may receive an additional injection (booster).

Adults above 50 years of age

There are no data in adults above 50 years of age. Ask your doctor for advice whether it is beneficial for you to receive Bexsero.

Do not exceed the recommended dose.

Adhere to the treatment recommended by your physician.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Bexsero may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

When Bexsero is given to you or your child, the very common side effects (may affect more than 1 in 10 users) that you or your child may experience (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 side effects

These may affect more than 1 in 10 people:

- fever (≥38ºC)
- loss of appetite
- tenderness at the injection site (including severe injection site tenderness resulting in crying when the injected limb is moved)
- painful joints
- skin rash (children aged 12 to 23 months) (uncommon after booster)
- sleepiness
- feeling irritable
- unusual crying
- vomiting (uncommon after booster)
- diarrhoea
- headache

Common side effects

These may affect up to 1 in 10 people:

- skin rash (infants and children 2 to 10 years of age)

Uncommon side effects

These may affect up to 1 in 100 people:

- high fever (≥ 40°C)

- seizures (including febrile seizures)
- dry skin
- paleness (rare after booster)

Rare side effects

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, and red eyes, lips, throat and tongue.
- itchy rash, skin rash

Adolescents (from 11 years of age) and adults

Very common side effects

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

Additional side effects:

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 muscle floppiness), less responsive than usual or lack of awareness, and paleness or bluish skin discoloration in young children.

Feeling faint or fainting.

Skin rash (adolescents from 11 years of age and adults).

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 lumps at the injection site (which may persist for more than one month).
Neck stiffness or uncomfortable sensitivity to light (photophobia), indicating meningeal irritation, has been sporadically reported shortly after vaccination. These symptoms have been of mild and transient nature.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Keep refrigerated (2°C-8°C). Do not freeze.
- Store in the original package in order to protect from light.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains:
  sucrose, sodium chloride, aluminium hydroxide, histidine, and water for injections.

Also see section 2 in this leaflet – "Important information about some of the ingredients in the medicine".

- What the medicine looks like and the contents of the package:
  Bexsero is a suspension for injection in a pre-filled syringe.
  The suspension is a white opalescent liquid.
  Pack sizes: one syringe or ten syringes with or without needles.
  Not all package sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GSK Vaccines S.r.l., Siena, Italy.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 155-59-34399

Revised in November 2021 according to MoH guidelines.

Bex PT V2A