Package leaflet: information for the user

Bexsero suspension for injection in pre-filled syringe
Meningococcal group B Vaccine (rDNA, component, adsorbed)

Read all of this leaflet carefully before you or your child receive this medicine because it contains important information for you or your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This vaccine has been prescribed for you or your child only.
- If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Bexsero is and what it is used for
2. What you need to know before you or your child receive Bexsero
3. How to use Bexsero
4. Possible side effects
5. How to store Bexsero
6. Contents of the pack and other information

1. What BEXSERO is and what it is used for

Bexsero is a Meningococcal group B Vaccine.

Bexsero contains four different components from the surface of the bacteria *Neisseria meningitidis* group B.

Bexsero is given to individuals from 2 months of age and older to help protect against disease caused by the *Neisseria meningitidis* group B bacteria. 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 the disease.

2. What you need to know before you or your child receive BEXSERO

Do NOT use Bexsero:

- If you or your child are allergic to the active substances or any of the other ingredients of this vaccine (listed in section 6).

Warnings and precautions

Talk to your doctor or nurse before you or your child receive Bexsero, 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.
- 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.

- 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.
- 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 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 your allergy when deciding if you or your child should receive Bexsero.

There are 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 hereditary defects of the body's natural defence 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.

Other medicines and Bexsero

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 C. 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 doctor for advice before Bexsero is given. 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 "Possible side effects" may temporarily affect the ability to drive or use machines.

Bexsero contains sodium chloride

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

3. How to use BEXSERO

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 course of injections.

Infants up 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.
- The first injection should be given no earlier than 3 months of age 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.

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.

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.

If you have any further questions on Bexsero, ask your doctor or nurse.

4. Possible side effects

Like all vaccines, this vaccine 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 (≥38ºC)
- loss of appetite
- tenderness or discomfort at the injection site (including severe injection site tenderness resulting in crying when injected limb is moved)
- painful joints
- skin rash (children aged 12 to 23 months) (uncommon after booster)
- sleepiness
- feeling irritable
- unusual crying
- vomiting
- diarrhea
- headache

Common (these may affect up to 1 in 10 people)
- skin rash (infants and children 2 to 10 years of age)

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

Adolescents (from 11 years of age) and adults

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:

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).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

5. How to store BEXSERO

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze.
Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your doctor or nurse how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bexsero contains

One dose (0.5 ml) contains:

Active substances:

Recombinant *Neisseria meningitidis* group B NHBA fusion protein [1, 2, 3]	50 micrograms
Recombinant *Neisseria meningitidis* group B NadA protein [1, 2, 3]	50 micrograms
Recombinant *Neisseria meningitidis* group B fHbp fusion protein [1, 2, 3]	50 micrograms
Outer membrane vesicles (OMV) from *Neisseria meningitidis* group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4 [2]	25 micrograms

[1] produced in *E. coli* cells by recombinant DNA technology
[2] adsorbed on aluminium hydroxide (0.5 mg Al^{3+})
[3] NHBA (Neisseria Heparin Binding Antigen), NadA (Neisserial adhesin A), fHbp (factor H binding protein)

Other ingredients:
Sodium chloride, histidine, sucrose and water for injections (see section 2 for further information on sodium and latex).

What Bexsero looks like and contents of the pack

Bexsero is a suspension for injection in pre-filled syringe (Type I glass) with a plunger stopper (Type I bromobutyl rubber) and with a protective tip cap (Type I or Type II rubber) with or without needles.

Pack sizes of 1 or 10 syringes.
The suspension is white opalescent liquid.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

GSK Vaccines S.r.l.
Via Fiorentina 1
53100 Siena
Italy.

Manufacturer:

GSK Vaccines S.r.l.
Bellaria-Rosia
53018 Sovicille (Siena)
Italy.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
GlaxoSmithKline Pharmaceuticals s.a./n.v.
Tél/Tel: + 32 10 85 52 00

Lietuva
GlaxoSmithKline Lietuva UAB
Tel: +370 5 264 90 00
info.lt@gsk.com

България
ГлаксоСмитКлайн ЕООД
Тел. + 359 2 953 10 34

Luxembourg/Luxemburg
GlaxoSmithKline Pharmaceuticals s.a./n.v.
Tél/Tel: + 32 10 85 52 00

Česká republika
GlaxoSmithKline s.r.o.
Tel: + 420 2 22 00 11 11
cz.info@gsk.com

Magyarország
GlaxoSmithKline Kft.
Tel.: + 36-1-2255300

Danmark
GlaxoSmithKline Pharma A/S
Tlf: + 45 36 35 91 00
dk-info@gsk.com

Malta
GlaxoSmithKline (Malta) Ltd
Tel: + 356 21 238131

Deutschland
GlaxoSmithKline GmbH & Co. KG
Tel: +49 (0)89 36044 8701
de.impfservice@gsk.com

Nederland
GlaxoSmithKline BV
Tel: + 31 (0)30 69 38 100
nlinfo@gsk.com

Eesti
GlaxoSmithKline Eesti OÜ
Tel: +372 667 6900
estonia@gsk.com

Norge
GlaxoSmithKline AS
Tlf: + 47 22 70 20 00
firmapost@gsk.no

Ελλάδα
GlaxoSmithKline A.E.B.E
Τηλ: + 30 210 68 82 100

España
GlaxoSmithKline, S.A.
Tel: + 34 902 202 700
es-ci@gsk.com

France
Laboratoire GlaxoSmithKline
Tél: + 33 (0) 1 39 17 84 44
diam@gsk.com

Hrvatska
GlaxoSmithKline d.o.o.
Tel.: + 385 (0)1 6051999

Ireland
GlaxoSmithKline (Ireland) Ltd
Tel: + 353 (0)1 495 5000

Ísland
Vistor hf.
Sími: +354 535 7000

Italia
GlaxoSmithKline S.p.A.
Tel: +39 04 59 21 81 11

Κύπρος
GlaxoSmithKline (Cyprus) Ltd
Τηλ: + 357 22 39 70 00
gskcyprus@gsk.com

Latvija
GlaxoSmithKline Latvia SIA
Tel: + 371 67312687
lv-epasts@gsk.com

Österreich
GlaxoSmithKline Pharma GmbH.
Tel: + 43 1 970 75-0
at.info@gsk.com

Polska
GSK Services Sp. z o.o.
Tel.: + 48 (22) 576 9000

Portugal
GlaxoSmithKline - Produtos Farmacêuticos, Lda.
Tel: + 351 21 412 95 00
FI.PT@gsk.com

România
GlaxoSmithKline (GSK) SRL
Tel: +40 (0)21 3028 208

Slovenija
GlaxoSmithKline d.o.o.
Tel: + 386 (0) 1 280 25 00
medical.x.si@gsk.com

Slovenská republika
GlaxoSmithKline Slovakia s.r.o.
Tel: + 421 (0)2 48 26 11 11
recepcia.sk@gsk.com

Suomi/Finland
GlaxoSmithKline Oy
Puh/Tel: + 358 10 30 30 30
Finland.tuoteinfo@gsk.com

Sverige
GlaxoSmithKline AB
Tel: + 46 (0)8 638 93 00
info.produkt@gsk.com

United Kingdom
GlaxoSmithKline UK
Tel: + 44 (0)800 221 441
customercontactuk@gsk.com

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

The following information is intended for healthcare professionals only:

Upon storage a fine off-white deposit may be observed in the pre-filled syringe containing the suspension.

Before use, the pre-filled syringe should be well shaken in order to form a homogeneous suspension.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. If two needles of different lengths are provided in the pack, choose the appropriate needle to ensure an intramuscular administration.

Do not freeze.
Bexsero must not be mixed with other vaccines in the same syringe.
Should concomitant administration of other vaccines be necessary, vaccines must be administered at separate injection sites.

Care must be taken to ensure that the vaccine is injected intramuscularly only.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.