PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

BEXSERO

Meningococcal group B vaccine (rDNA, component, adsorbed)

Suspension for Injection

Contains sugar (sucrose 10 mg/0,5 mL dose)

Read all of this leaflet carefully before you/your child receive(s) BEXSERO:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- BEXSERO has been prescribed for you/your child personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

This leaflet has been written assuming the person receiving the vaccine is reading it, but it can be given to adolescents and children, so you may be reading it for your child.

What is this leaflet:

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).

As with all vaccines, BEXSERO may not fully protect all people who are vaccinated.

BEXSERO helps your body make its own protection (antibodies). This will protect you against this disease.

The vaccine cannot cause the disease that it protects you from.

2. What you need to know before BEXSERO is given to you:

BEXSERO should not be administered to you:

- if you are allergic (hypersensitive) to BEXSERO or any of the ingredients contained in BEXSERO (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Check with your doctor if you think any of these apply to you.

Warnings and precautions:

Take special care with BEXSERO:

Tell your doctor or healthcare provider before being given the injection:

- if you have a severe infection with a high temperature. In these cases, the vaccination may be postponed until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first
- if you 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

- 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
- if you have an allergy to the antibiotic kanamycin, talk to your doctor or nurse first.

Fainting can occur following, or even before, any needle injection. Therefore, tell the doctor or nurse if you fainted with a previous injection.

Tell your doctor or nurse if you know that you are allergic to 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.

The safety and efficacy of BEXSERO in individuals above 50 years of age have not been established. There are limited data on the use of BEXSERO in patients with chronic medical conditions or with weakened immunity. Persons with a weakened immune system, for example due to human immunodeficiency virus (HIV) or due to medicines that suppress the immune system, may not get the full benefit from BEXSERO.

Other medicines and BEXSERO:

Always tell your healthcare provider if you are taking any other medicne. This includes all complementary or traditional medicines.

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. A different injection site will be used for each type of vaccine.

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, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before being given BEXSERO.

Driving and using machines:

BEXSERO has no or negligible influence on your ability to drive or use machines. However, some of the effects mentioned under section 4 may temporarily affect your ability to drive or use machines.

BEXSERO contains sucrose:

If you have been told by your doctor that you have an intolerance to some sugars, tell your doctor before you are given BEXSERO.
BEXSERO contains sucrose, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How BEXSERO should be given:

BEXSERO (0,5 mL) will be given to you 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 complete the course of injections.

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 interval between injections 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 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:

Your child should receive two injections of the vaccine with an interval of 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:

You should receive two injections of the vaccine with an interval of at least 1 month.

You may receive an additional injection (booster).

Adults above 50 years of age:

The safety and efficacy of BEXSERO in individuals above 50 years of age have not been established. 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.

If you miss a dose of BEXSERO:

Since a healthcare provider will administer BEXSERO, it is unlikely that the dose will be missed. If you miss a scheduled injection, it is important that you make another appointment.

If you stop receiving BEXSERO:

Make sure you finish the complete vaccination course. If not, you may not be fully protected against the diseases.

4. Possible side effects:

BEXSERO can have side effects.

Not all side effects reported for BEXSERO are included in this leaflet. Should your general health worsen or if you experience any untoward effects after being given BEXSERO, please consult your healthcare provider for advice.

Allergic reaction: If any of the following happens, stop receiving BEXSERO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- enlarged lymph nodes
- itchy rash of your hands and feet
- swelling of your eyes and face
- difficulty in breathing or swallowing
- sudden drop in blood pressure and loss of consciousness.
- skin rash (adolescents from 11 years of age and adults).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BEXSERO. You may need urgent medical attention or hospitalisation. These reactions will usually occur before leaving the healthcare provider. However, if you or your child gets any of these symptoms you should contact a doctor urgently.

When BEXSERO is given to you or your child, the most common side effects that you or your child may get (reported in all age groups) are:

- pain/tenderness at the injection site, redness of your skin at the injection site, swelling of your skin at the injection site, hardness of your skin at the injection site.

Tell your doctor if you notice any of the following:

Infants and children (up to 10 years of age):

Frequent side effects:

- loss of appetite
- sleepiness
- unusual crying
- headache
- being sick (vomiting) (uncommon after booster)
- diarrhoea
- skin rash (children aged 12 to 23 months) (uncommon after booster)
- skin rash (infants and children 2 to 10 years of age)
- painful joints
- fever (≥ 38 ºC)
- tenderness at the injection site (including severe injection site tenderness resulting in crying when injected limb is moved)
- feeling irritable.

Less frequent side effects:

- seizures (including febrile seizures)
- paleness (rare after booster)
- dry skin
- high fever (≥ 40 °C).

Other side effects that can occur:

- 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:

Frequent side effects include:

- headache
- feeling sick (nausea)
- painful muscles and joints
- pain at the injection site resulting in inability to perform normal daily activity
- generally feeling unwell.

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)

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

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the ***6.04 Adverse Drug Reaction Reporting Form***, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BEXSERO.

5. How to store BEXSERO:

Store all medicines out of the reach of children.

- Store in a refrigerator (+2 °C to +8 °C).
- Do not freeze.
- Store in the original package in order to protect from light.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist 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:

1 dose (0,5 mL) contains:

- *The active substances are:*

Recombinant *Neisseria meningitidis* group B NHBA fusion protein [1, 2, 3]	50 µg
Recombinant *Neisseria meningitidis* group B NadA protein [1, 2, 3]	50 µg
Recombinant *Neisseria meningitidis* group B fHbp fusion protein [1, 2, 3]	50 µg
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 µg

[1] produced in *E. coli* cells by recombinant DNA technology

[2] Adsorbed on aluminium hydroxide (0,5 mg Al^{3+})

[3] NHBA (Neisserial Heparin Binding Antigen), NadA (*Neisseria* adhesin A), fHbp (factor H binding protein)

Contains sugar (sucrose 10 mg/0,5 mL).

- *The other ingredients are:*

Sodium chloride, histidine, sucrose, water for injections.

What BEXSERO looks like and contents of the pack:

BEXSERO is a white opalescent suspension for injection in pre-filled syringe with a plunger stopper and with a protective tip cap with or without needles.

Pack sizes of 1 or 10 syringes.

Not all pack sizes may be marketed.

Instructions for use:

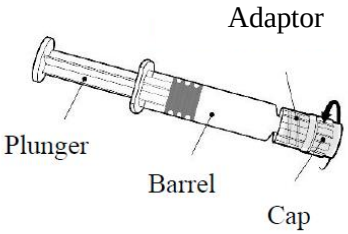
The following information is intended for medical or healthcare professionals only:

Upon storage of the suspension, a fine off-white deposit may form.

Shake the vaccine well before use to form a homogeneous suspension.

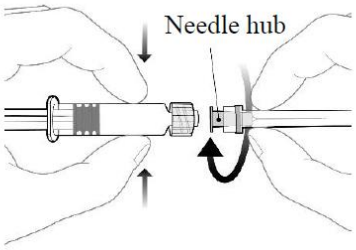
The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. If two needles of different lengths are provided in the pack, choose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

Instructions for the pre-filled syringe:



Hold the syringe by the barrel, not by the plunger.

Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, connect the hub to the Adaptor and rotate a quarter turn clockwise until you feel it lock.

Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

Disposal:

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

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

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PASIËNTINLIGTINGSVOUBILJET

SKEDULERINGSTATUS:

S4

BEXSERO

Meningokokkus-groep B-vaksien (rDNA, komponent, geadsorbeer)

Suspensie vir Inspuiting

Bevat suiker (sukrose teen 10 mg/0,5 mL- dosis)

Lees hierdie hele voubiljet aandagtig deur voordat u/u kind BEXSERO ontvang:

- Hou hierdie voubiljet. U sal dit moontlik weer moet lees.
- As u enige verdere vrae het, moet u asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- BEXSERO is vir u/u kind persoonlik voorgeskryf en u moenie u medisyne met ander persone deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as u s'n.

Hierdie voubiljet is so geskryf dat daar aangeneem word dat die persoon wat die vaksien ontvang, die voubiljet lees, maar dit kan ook aan adolessente en kinders gegee word en dit is moontlik dat u dit vir u kind sal moet voorlees.

Wat in hierdie voubiljet vervat word:

- **Wat BEXSERO is en waarvoor dit gebruik word:**

BEXSERO is ’n meningokokkus groep B-vaksien.

BEXSERO bevat vier verskillende komponente vanaf die oppervlak van die bakterieë wat groep B-*Neisseria meningitidis* genoem word.

BEXSERO word gegee aan individue vanaf die ouderdom van 2 maande en ouer om te help beskerm teen siekte wat veroorsaak word deur die groep B-*Neisseria meningitidis*-bakterieë. Hierdie bakterieë kan ernstige, en soms lewensgevaarlike, infeksies soos meningitis (inflammasie van die brein- en rugmurgvlies) en sepsis (bloedvergifting) veroorsaak.

Soos vir alle vaksiene is dit moontlik dat BEXSERO nie alle persone wat daarmee gevaksineer is ten volle sal beskerm nie.

BEXSERO help u liggaam om sy eie beskerming (teenliggaampies) te vervaardig. Dit sal u teen hierdie siekte beskerm.

Die vaksien kan nie die siekte veroorsaak waarteen dit u beskerm nie.

2. Wat u moet weet voordat BEXSERO inspuiting aan u gegee word:

BEXSERO moenie in die volgende gevalle aan u gegee word nie:

- indien u allergies (hipersensitief) vir BEXSERO of vir enige van die bestanddele van BEXSERO is (dit word in afdeling 6 uiteengesit). Tekens van ’n allergiese reaksie kan moontlik ’n jeukende veluitslag, kortasemigheid en swelling van die gesig of tong insluit.

Maak seker by u dokter as u dink dat enige hiervan op u van toepassing is.

Waarskuwings en voorsorgmaatrëels:

Wees in die volgende gevalle besonder versigtig met BEXSERO:

U dokter moet die volgende weet voordat BEXSERO aan u gegee word:

- indien u ’n ernstige infeksie met hoë koors het. In sulke gevalle kan die vaksinering moontlik uitgestel word tot u herstel het. ’n Geringe infeksie, soos ’n verkoue, behoort nie ’n probleem te wees nie, maar praat eers met u dokter

- indien u behandeling ontvang wat die deel van die immuunstelsel blokkeer wat bekend staan as komplementaktivering, soos ekulisumab. Selfs as u met BEXSERO gevaksineer is, het u steeds ’n groter risiko vir siekte wat deur die groep B-Neisseria meningitidis-bakterieë veroorsaak word.
- indien u kind voortydig gebore is (voor of teen 28 weke van swangerskap), veral as u kind asemhalingsprobleme ervaar het, moet u asseblief vir u dokter inlig. Dit kan moontlik gedurende die eerste drie dae ná vaksinering algemeen wees vir hierdie babas om op te hou asemhaal, of om vir ’n kort rukkie onreëlmatig asem te haal, en hulle kan moontlik spesiale monitering nodig hê.
- indien u allergies is vir die antibiotikum kanamisien, moet u eers u dokter of verpleegkundige inlig.

Floute kan voorkom ná, of selfs voor, enige inspuiting met ’n naald; sê dus vir die dokter of verpleegkundige as u gedurende ’n vorige inspuiting flou geval het.

Sê vir u dokter of verpleegkundige as u weet dat u allergies is vir lateks. Alhoewel daar geen natuurlike rubberlateks in die spuitpuntdoppie opgespoor is nie, is die veilige gebruik van BEXSERO deur latekssensitiewe individue nie vasgestel nie.

Die veiligheid en doeltreffendheid van BEXSERO by individue ouer as 50 jaar oud is nie vasgestel nie. Daar is beperkte data oor die gebruik van BEXSERO deur pasiënte met chroniese mediese toestande of diegene met verswakte immuniteit. Mense met ’n verswakte immuunstelsel, byvoorbeeld as gevolg van menslike immuniteitsgebreksvirus (MIV)infeksie of medisyne wat die immuunstelsel onderdruk, kan moontlik nie die volle voordeel van BEXSERO kry nie.

Ander medisynes en BEXSERO:

Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne neem. (Dit sluit alle aanvullende of tradisionele medisyne in.)

BEXSERO kan op dieselfde tyd gegee word as enige van die volgende vaksien komponente: witseerkeel (difterie), klem-in-die-kaak (tetanus), kinkhoes (pertussis), tipe B-*Haemophilus*

influenzae, polio, hepatitis B, pneumokokkus, masels, pampoentjies, Duitse masels (rubella), waterpokkies, en meningokokkus A, C, W en Y. Daar sal vir elke tipe vaksien ’n ander inspuitplek gebruik word.

U dokter of verpleegkundige kan u moontlik vra om ten tyde wat BEXSERO gegee word, en ná dit gegee is, medisynes aan u kind te gee om koors af te bring. Dit sal help om van die newe-effekte van BEXSERO te verminder.

Swangerskap, borsvoeding en vrugbaarheid:

As u swanger is of borsvoed, dink dat u dalk swanger kan wees of as u van plan is om swanger te raak, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat BEXSERO aan u gegee word.

BEXSERO bevat sukrose:

As u dokter vir u ingelig het dat u ’n intoleransie vir sekere soorte suikers het, sê vir u dokter voordat BEXSERO aan u gegee word.

BEXSERO bevat sukrose wat moontlik ’n uitwerking kan hê op die beheer van u bloedsuiker as u aan diabetes mellitus ly.

3. Hoe BEXSERO gegee moet word:

BEXSERO (0,5 mL) sal deur ’n dokter of verpleegkundige aan u gegee word. Dit sal in ’n spier ingespuit word; gewoonlik in die bobeen vir babas, of die boarm vir kinders, adolessente en volwassenes.

Dit is belangrik om die instruksies van die dokter of verpleegkundige te volg sodat u die kursus inspuitings voltooi.

Babas van 2 maande tot 5 maande oud ten tyde van die eerste dosis:

U kind moet ’n aanvanklike kursus van twee of drie inspuitings van die vaksien ontvang, gevolg deur ’n bykomende inspuiting (versterkerdosis).

- Die interval tussen inspuitings moet minstens 2 maande wees as twee aanvanklike dosisse gegee word, of minstens 1 maand as drie aanvanklike dosisse gegee word.
- ’n Versterkerdosis sal gedurende die tweede lewensjaar gegee word ná ’n interval van minstens 6 maande ná die laaste inspuiting van die aanvanklike kursus.

Babas van 6 maande tot 11 maande oud ten tyde van die eerste dosis:

Babas van 6 maande tot 11 maande oud moet twee inspuitings van die vaksien ontvang gevolg deur ’n bykomende inspuiting (versterkerdosis).

- Die interval tussen elke inspuiting moet minstens 2 maande wees.
- ’n Versterkerdosis sal gedurende die tweede lewensjaar gegee word ná ’n interval van minstens 2 maande ná die tweede inspuiting.

Kinders van 12 maande tot 23 maande oud ten tyde van die eerste dosis:

Kinders van 12 maande tot 23 maande oud moet twee inspuitings van die vaksien ontvang gevolg deur ’n bykomende inspuiting (versterkerdosis).

- Die interval tussen elke inspuiting moet minstens 2 maande wees.
- ’n Versterkerdosis sal ná ’n interval van 12 tot 23 maande ná die tweede inspuiting gegee word.

Kinders van 2 jaar tot 10 jaar oud ten tyde van die eerste dosis:

U kind moet twee inspuitings van die vaksien teen ’n interval van minstens 1 maand ontvang.
U kind kan moontlik ’n bykomende inspuiting (versterkerdosis) ontvang.

Adolessente en volwassenes vanaf 11 jaar oud ten tyde van die eerste dosis:

U moet twee inspuitings van die vaksien teen ’n interval van minstens 1 maand ontvang.
U kan moontlik ’n bykomende inspuiting (versterkerdosis) ontvang.

Volwassenes ouer as 50 jaar oud:

Die veiligheid en doeltreffendheid van BEXSERO by individue ouer as 50 jaar oud, is nie vasgestel nie. Vra u dokter vir advies rakende die voordeligheid om BEXSERO te ontvang.

As u enige verdere vrae oor BEXSERO het, moet u asseblief u dokter of verpleegkundige vra.

As u ’n dosis BEXSERO oorslaan:

Aangesien 'n gesondheidsorgverskaffer BEXSERO sal administreer, is dit onwaarskynlik dat die dosis gemis sal word. As u ’n geskeduleerde inspuiting misloop, is dit belangrik dat u ’n nuwe afspraak maak.

As u ophou om BEXSERO te ontvang:

Maak seker dat u die hele vaksineringskurses voltooi. As u dit nie doen nie, is dit moontlik dat u nie volledige beskerming teen die siekte sal kry nie.

4. Moontlike newe-effekte:

BEXSERO kan newe-effekte veroorsaak.

Nie al die newe-effekte wat vir BEXSERO aangemeld is, word by hierdie voubiljet ingesluit nie. Sou u algemene gesondheid agteruitgaan, of as u enige nadelige effekte ervaar nadat BEXSERO aan u gegee is, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgkundige vir advies.

Allergiese reaksies: Indien enige van die volgende gebeur, hou op om BEXSERO te ontvang, vertel jou dokter dadelik of gaan na die ongevalle-afdeling van u naaste hospitaal:

- vergrote limfkliere
- jeukende uitslag van u hande en voete
- swelling van u oë en gesig
- asemhalingsprobleme of slukprobleme

- skielike daling van die bloeddruk en verlies aan bewussyn
- veluitslag (adolessente van 11 jaar oud en volwassenes)

Dit is alles baie ernstige newe-effekte. As u dié simptome ervaar, het u moontlik ’n ernstige allergiese reaksie op BEXSERO ervaar. U kan moontlik dringend mediese hulp nodig hê of in die hospitaal opgeneem moet word. Dié reaksies sal gewoonlik voorkom voordat u die dokter se spreekkamer verlaat. As u of u kind egter enige van hierdie simptome ervaar, moet u dringend ’n dokter kontak.

Wanneer BEXSERO aan u of u kind gegee word, is die algemene newe-effekte wat u of u kind moontlik kan ervaar (wat vir alle ouderdomsgroepe aangemeld is):

- pyn/teerheid by die inspuitplek, rooiheid van u vel by die inspuitplek, swelling van u vel by die inspuitplek, hardheid van u vel by die inspuitplek.

Sê vir u dokter as u een van die volgende opmerk:

Babas en kinders (tot 10 jaar oud):

Algemene newe-effekte:

- verlies aan eetlus
- slaperigheid
- buitengewone gehuil
- hoofpyn
- siek wees (braking) (nie-algemeen ná die versterkerdosis)
- diarree
- veluitslag (kinders van 12 tot 23 maande) (nie-algemeen ná die versterkerdosis)
- veluitslag (babas en kinders van 2 tot 10 jaar oud)
- pynlike gewrigte
- koors (≥ 38 °C)

- teerheid by die inspuitplek (insluitend ernstige inspuitplekteerheid wat veroorsaak dat die kind huil wanneer die ingespuite ledemaat beweeg word)
- voel prikkelbaar.

Nie-algemene newe-effekte:

- aanvalle (insluitend koorsstuipe)
- bleekheid (seldsaam ná die versterkerdosis)
- droë vel
- hoë koors (≥ 40 °C).

Ander newe-effekte wat moontlik kan voorkom:

- Kawasaki-siekte wat simptome kan insluit soos koors wat vir langer as vyf dae duur, geassosieer met ’n veluitslag op die bolyf en soms gevolg deur die afskilfering van die vel op die hande en vingers, geswelde kliere in die nek, rooi oë, lippe, keel en tong
- uitslag wat jeuk, veluitslag.

Adolessente (vanaf 11 jaar oud) en volwassenes:

Algemene newe-effekte sluit in:

- hoofpyn
- voel mislik (naarheid)
- pyn in die spiere en gewrigte
- pyn by die inspuitplek wat daartoe lei dat mens nie normale daaglikse aktiwiteite kan verrig nie
- voel oor die algemeen ongesteld.

Newe-effekte wat gedurende bemarkte gebruik aangemeld is, sluit in:

- allergiese reaksies wat moontlik ernstige swelling van die lippe, mond of keel (wat moontlik slukprobleme kan veroorsaak) kan insluit; asemhalingsprobleme met asemfluit of hoes, veluitslag, verlies aan bewussyn en baie lae bloeddruk
- ineenstorting (skielike aanvang van spierslapheid), minder reageer as gewoonlik of gebrek aan bewustheid, en bleekheid of blouerige velverkleuring by klein kindertjies, voel flou of val flou
- koors (adolessente vanaf 11 jaar oud en volwassenes), inspuitplekreaksies soos ekstensiewe swelling van die ingespuite ledemaat, blase by of rondom die inspuitplek en ’n harde knop by die inspuitplek (wat moontlik vir langer as een maand kan voortduur)

Sê asseblief vir u dokter of apteker as enige van dié newe-effekte ernstig raak, of as u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie.

Aanmelding van newe-effekte:

Praat met u dokter, apteker of verpleegkundige as u newe-effekte ervaar. U kan ook newe-effekte by SAHPRA aanmeld deur die “**6.04 Adverse Drug Reaction Reporting Form**” te gebruik wat aanlyn onder SAHPRA se publikasies beskikbaar is: https://www.sahpra.org.za/Publications/index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van BEXSERO te verskaf.

5. Hoe om BEXSERO te bewaar:

Hou hierdie medisyne buite die bereik van kinders.

- Bewaar in ’n yskas (+2 °C tot +8 °C).
- Moenie vries nie.
- Bewaar dit in die oorspronklike verpakking om dit teen lig te beskerm.
- Moenie hierdie medisyne gebruik ná die vervaldatum wat op die boksie gedruk staan nie. Die vervaldatum verwys na die laaste dag van daardie maand.

Moenie medisynes in afvoerwater of huishoudelike vullis weggooi nie. Vra u apteker hoe om medisynes wat u nie meer gebruik nie, weg te gooi. Dié maatreëls sal die omgewing help beskerm.

6. Inhoud van die pakkie en ander inligting:

Wat BEXSERO bevat:

1 dosis (0,5 mL) bevat:

- *Die aktiewe stowwe is:*

Rekombinante groep B-*Neisseria meningitidis*-fusieproteïen [1, 2, 3]	50 µg
Rekombinante groep B-*Neisseria meningitidis*-NadA-proteïen [1, 2, 3]	50 µg
Rekombinante groep B-*Neisseria meningitidis*-fHbp-fusieproteïen [1, 2, 3]	50 µg
Buitenste membraanvesikels (OMV) van groep B-*Neisseria meningitidis* NZ98/254-stam gemeet as die hoeveelheid totale proteïen wat PorA P1.4 bevat [2]	25 µg

1 word in *E. coli*-selle geproduseer met behulp van rekombinante DNS-tegnologie

2 Geadsorbeer op aluminiumhidroksied (0,5 mg Al^{3+})

3 NHBA (Neisserial-heparienbindende antigeen), NadA (*Neisseria*-adhesien A), fHbp (faktor-H-bindende proteïen)

Bevat suiker (10 mg/0,5 mL sukrose).

- *Die ander bestanddele is:*

natriumchloried, histidien, sukrose, water vir inspuitings.

Hoe BEXSERO lyk, en wat die inhoud van die pakkie is:

BEXSERO is ’n wit, melkagtige suspensie vir inspuiting in ’n voorafgevulde spuit met ’n plunjerprop en ’n beskermende puntdoppie met of sonder naalde.

Pakgroottes van 1 of 10 spuite.

Nie al die pakgroottes word noodwendig bemark nie.

Instruksies vir gebruik:

Die volgende inligting is slegs vir mediese of gesondheidsorgkundiges bedoel:

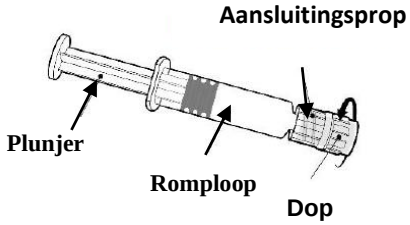
Gedurende bewaring van die suspensie kan ’n fyn, naaswit neerslag moontlik vorm.

Skud die vaksien goed voordat dit gebruik word sodat dit ’n eenvormige suspensie vorm.

Die vaksien moet visueel ondersoek word vir enige vreemde deeltjies en verkleuring voordat dit toegedien word. As daar enige vreemde deeltjies en/of afwykings in terme van die fisieke voorkoms waargeneem word, moet die vaksien nie toegedien word nie.

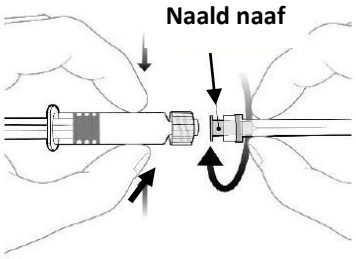
As twee naalde van verskillende lengtes in die pakkie voorsien word, kies die toepaslike naald om binnespierse toediening te verseker.

Instruksies vir die vooraf gevulde spuit:



Hou die spuit by die romploop (nie aan die plunjer nie).

Skroef die dop los deur dit antikloksgewys te draai.



Om die naald vas te maak, koppel die naald naaf aan die Aansluitingsprop en draai 'n kwart draai kloksgewys totdat jy voel hoe dit sluit.

Moenie die plunjer uit die romploop trek nie. As dit gebeur, moenie die vaksien toedien nie

Wegdoening:

Daar moet in ooreenstemming met plaaslike vereistes weggedoen word met alle ongebruikte produk of afvalmateriaal.

Houer van die registrasiesertifikaat:

GlaxoSmithKline South Africa (Edms) Beperk.

Bridgeway Straat No. 1

Bridgeways Distrik

Century City

Kaapstad 7441

Die voubiljet was laas hersien op:

04 Julie 2024

Registrasienommer:

54/30.2/0803

GDS 14 and v16