PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

BEYFORTUS 50 mg solution for injection

BEYFORTUS 100 mg solution for injection

Nirsevimab

BEYFORTUS 50 mg contains sugar (21 mg sucrose per 0,5 mL solution).

BEYFORTUS 100 mg contains sugar (41 mg sucrose per 1 mL solution).

Read all of this leaflet carefully before you start using BEYFORTUS.

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

What is in this leaflet

1. What BEYFORTUS is and what it is used for

What BEYFORTUS is

BEYFORTUS is a medicine given as an injection to protect babies against respiratory syncytial virus (RSV). RSV is a common respiratory virus that usually causes mild symptoms comparable to the common cold. However, especially in babies and older adults, RSV can cause severe illness, including bronchiolitis (inflammation of the small airways in the lung) and pneumonia (infection of the lungs) that may lead to hospitalisation or even death. The virus is usually more common during the winter.

BEYFORTUS contains the active ingredient nirsevimab which is an antibody (a protein designed to attach to a specific target) that attaches to a protein that RSV needs to infect the body. By attaching to this protein, BEYFORTUS blocks its action, thereby stopping the virus from entering and infecting human cells.

What is BEYFORTUS used for

BEYFORTUS is a medicine to protect your child from getting RSV disease.

2. What you need to know before your child is given BEYFORTUS

You must not receive BEYFORTUS if:

- Your child should not use BEYFORTUS if he or she is allergic (hypersensitive) to nirsevimab or any of the other ingredients of BEYFORTUS (listed in section 6).

If your child shows signs of a severe allergic reaction contact the doctor immediately.

Warnings and precautions

Tell your doctor or seek medical help immediately if you notice any signs of an **allergic reaction**, such as:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat

- severe itching of the skin, with a red rash or raised bumps

Talk to your health care provider before your child is given BEYFORTUS if they have low numbers of blood platelets (which help blood clotting), a bleeding problem or bruise easily or if they are taking an anticoagulant (a medicine to prevent blood clots).

Children and adolescents

Do not give BEYFORTUS to children between the age of 2 and 18 years of age because it has not been studied in this group.

Other medicines and BEYFORTUS:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
Please consult with your doctor, pharmacist or health care provider for advice if you need to take any other medicines.

BEYFORTUS is not known to interact with other medicines.

BEYFORTUS may be given at the same time as vaccines that are part of the national immunisation program.

Pregnancy and breastfeeding

BEYFORTUS is only intended for use in newborns and infants.

Driving and using machines

BEYFORTUS is only intended for use in newborns and infants.

3. How BEYFORTUS is given

Always use medicines exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with any other person.

BEYFORTUS is given by a doctor, pharmacist or nurse as a single injection in the muscle. It is usually given in the outer part of the thigh.

The recommended dose is 50 mg for children weighing less than 5 kg and 100 mg for children weighing 5 kg or more.

BEYFORTUS should be given before the RSV season. The virus is usually more common during the winter (known as the RSV season). If your child is born during the winter, BEYFORTUS should be given after birth.

If your child is to have a heart operation (cardiac surgery), he or she may be given an extra dose of BEYFORTUS after the operation to ensure they have adequate protection over the remainder of the RSV season.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

If your child is given more BEYFORTUS than he or she should

BEYFORTUS will be administered to your child by your doctor or nurse. If your child is accidentally given too much (an overdose), your doctor will treat and monitor your side effects.

4. Possible side effects

BEYFORTUS can have side effects.

Not all side effects reported for BEYFORTUS are included in this leaflet. Should your child’s

general health worsen or if your child experience any untoward effects while he/she is receiving BEYFORTUS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens to your child while receiving BEYFORTUS, tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

These are all very serious side effects. If your child has them, they may have had a serious reaction to BEYFORTUS. Your child my need urgent medical attention.

Tell your doctor if you note any of the following side effects in your child:

Uncommon side effects:

- rash
- injection site reaction (i.e. redness, swelling, and pain where the injection is given)
- fever

If you notice any side effects not mentioned in this leaflet, please inform your doctor, nurse or other health care provider.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email), https://ae.reporting.sanofi/ (web portal) or +27 11 256 3700 (tel), or
- 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 BEYFORTUS.

5. How to store BEYFORTUS

Store all medicines out of reach of children.

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

Keep the pre-filled syringe in the outer carton to protect from light.

Do not shake or expose to direct heat.

Do not use after the expiry date stated on the label and carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Any waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What BEYFORTUS contains

The active substance of BEYFORTUS is nirsevimab.

BEYFORTUS 50 mg: One pre-filled syringe of 0,5 mL solution contains 50 mg nirsevimab.

BEYFORTUS 100 mg: One pre-filled syringe of 1 mL solution contains 100 mg nirsevimab.

The other ingredients are L-histidine, L-histidine hydrochloride, L-arginine hydrochloride, sucrose, polysorbate 80, and water for injections.

What BEYFORTUS looks like and contents of the pack

BEYFORTUS is a colourless to yellow solution for injection.

BEYFORTUS is packed in a siliconised luer lock type I glass pre-filled syringe with a FluroTec-coated plunger stopper.

BEYFORTUS 50 mg: Each pre-filled syringe with a purple plunger rod contains 0,5 mL solution.

BEYFORTUS 100 mg: Each pre-filled syringe with a light blue plunger rod contains 1 mL solution.

Pack sizes:

- 1 or 5 pre-filled syringe(s) without needles.
- 1 pre-filled syringe packaged with two separate needles of different sizes.

Not all pack sizes are marketed.

Holder of the certificate of registration

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