Package leaflet: Information for the user

Beyfortus® 50 mg solution for injection in pre-filled syringe
Beyfortus® 100 mg solution for injection in pre-filled syringe
nirsevimab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects your child may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before your child is given this medicine because it contains important information for you and your child.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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 Beyfortus is 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

Your child should not use Beyfortus if he or she is allergic to nirsevimab or any of the other ingredients of this medicine (listed in section 6).
Inform your child's doctor, pharmacist or nurse if this applies to your child. If you are not sure**,** check with your child's doctor, pharmacist or nurse before the medicine is given.
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 healthcare 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 this medicine 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
Beyfortus is not known to interact with other medicines. However, tell your doctor, pharmacist or nurse if your child is taking, has recently taken or might take any other medicines.

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

3. How and when Beyfortus is given

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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects can include:

Uncommon (may affect up to 1 in 100 children)

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

Reporting of side effects
If your child gets 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 via the Yellow Card

Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Beyfortus

Your doctor, pharmacist or nurse is responsible for storing this medicine and disposing of any unused product correctly. The following information is intended for healthcare professionals.

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

Do not use this medicine 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). After removal from the refrigerator, Beyfortus must be protected from light and used within 8 hours or discarded.

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

Do not freeze, shake or expose to direct heat.

Any unused medicine or 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 is nirsevimab.
  - One pre-filled syringe of 0.5 mL solution contains 50 mg nirsevimab.
  - 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 available as:

- 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 may be marketed.

Marketing Authorisation Holder
AstraZeneca UK Limited
1 Francis Crick Avenue
Cambridge
CB2 0AA
UK

Distributed by
Aventis Pharma Limited t/a Sanofi
410 Thames Valley Park Drive
Reading
RG6 1PT
United Kingdom

Manufacturer
AstraZeneca AB
Gärtunavägen
SE-151 85 Södertälje
Sweden

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Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000

Please be ready to give the following information:

Product name	**Reference number**
Beyfortus 50 mg solution for injection in pre-filled syringe	17901/0370
Beyfortus 100 mg solution for injection in pre-filled syringe	17901/0371

This is a service provided by the Royal National Institute of the Blind.

The following information is intended for healthcare professionals only:

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Visually inspect Beyfortus for particulate matter and discolouration prior to administration. Beyfortus is a clear to opalescent, colourless to yellow solution. Do not inject Beyfortus if the liquid is cloudy, discoloured, or it contains large particles or foreign particulate matter.

Do not use if the Beyfortus pre-filled syringe has been dropped or damaged or the security seal on the carton has been broken.

Administer the entire contents of the pre-filled syringe as an intramuscular injection, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve.