

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

BEYFORTUS®

Nirsevimab injection

Read this carefully before your child starts taking **BEYFORTUS** and each time you get a dose. This leaflet is a summary and will not tell you everything about this drug. Talk to your child's healthcare professional about your child's medical condition and treatment and ask if there is any new information about **BEYFORTUS**.

What is BEYFORTUS used for?

BEYFORTUS protects your baby from getting respiratory syncytial virus (RSV) disease in their first RSV season. It may also be given to children less than 2 years of age who are vulnerable to severe RSV disease in their second RSV season.

RSV is a common respiratory virus that usually causes mild symptoms (cold-like illness) but can cause severe illness, including bronchiolitis (inflammation of the small airways in the lung) and pneumonia (infection of the lungs) that may lead to hospitalization or even death. The virus is usually more common during the winter (known as the RSV season), but it may begin earlier or last longer in certain parts of the country. Your healthcare professional can tell you when the RSV season starts in your area.

How does BEYFORTUS work?

BEYFORTUS contains the active ingredient nirsevimab which is a long-acting antibody that blocks the protein that RSV needs to infect the body. BEYFORTUS stops the virus from entering and infecting human cells and provides direct and timely protection against RSV disease to last for at least 5 months, corresponding to a typical RSV season.

What are the ingredients in BEYFORTUS?

Medicinal ingredient: nirsevimab

Non-medicinal ingredients: L-arginine hydrochloride, L-histidine, L-histidine hydrochloride, polysorbate 80, sucrose, and water for injection.

BEYFORTUS does not contain any preservatives.

BEYFORTUS comes in the following dosage form:

Solution for injection.

One single-use, pre-filled syringe of 0.5 mL solution contains 50 mg nirsevimab.

One single-use, pre-filled syringe of 1 mL solution contains 100 mg nirsevimab.

Do not use BEYFORTUS if:

- your child is allergic to nirsevimab or any of the other ingredients of this medicine (see What are the ingredients in BEYFORTUS). If this applies to your child, or if you are not sure, check with your child's healthcare professional.

To help avoid side effects and ensure proper use, talk to your child's healthcare professional before your child is given BEYFORTUS. Talk about any health conditions or problems your child may have, including if they:

- have low numbers of blood platelets (which help blood clotting), a bleeding problem or bruise easily or are taking an anticoagulant medicine (to prevent blood clots).

In certain chronic health conditions, where too much protein is lost via the urine or the gut, for example nephrotic syndrome and chronic liver disease, the level of protection of BEYFORTUS may be reduced.

Tell your child's healthcare professional or seek medical help right away 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

Tell your child's healthcare professional about all the medicines your child takes, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

BEYFORTUS is not known to interact with other medicines. However, tell your child's healthcare professional if your child is taking, has recently taken or might take any other medicines.

BEYFORTUS may be given at the same time as vaccines during the same visit.

How to take BEYFORTUS:

BEYFORTUS is given by a healthcare professional as a single injection in the muscle. It is usually given in the outer part of the thigh.

BEYFORTUS should be given before the RSV season. If your child is born during the RSV season, BEYFORTUS should be given as soon as possible after birth.

Usual dose:

The recommended dose is:

- 50 mg for babies weighing less than 5 kg and 100 mg for babies weighing 5 kg or more in their first RSV season.
- 200 mg for children who are vulnerable to severe RSV disease in their second RSV season (given as 2 x 100 mg injections).

If your child is having a heart operation (cardiac surgery), he or she may be given an extra dose of BEYFORTUS after the operation.

If you have any further questions on the use of this medicine, ask your child's healthcare professional.

Overdose:

If you think your child has taken too much BEYFORTUS, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using BEYFORTUS?

These are not all the possible side effects your child may have when taking BEYFORTUS. If your child experiences any side effects not listed here, tell your child's healthcare professional.

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

Not Known (cannot be estimated from available data)

- Allergic reactions

If your child has a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with his/her daily activities, tell your child's healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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 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 heat.

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

If you want more information about BEYFORTUS:

- Talk to your child's healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website:
<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug->

[product-database.html](#); the distributor's website www.sanofi.com/en/canada, or by calling 1-800-265-7927.

- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at www.sanofi.com/en/canada.

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