

A woman with dark hair, wearing a pink sweater, is sitting and holding a baby on her lap. The baby is wearing a blue cable-knit sweater and light blue pants. The woman is looking down at the baby with a gentle expression. The background is a soft-focus indoor setting.

sanofi

**Help protect infants in
their first season from
RSV, with Beyfortus^{®*}†**

Now available!

**Beyfortus[®].
Before RSV.**

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.

 **Beyfortus[®]**
(nirsevimab)

* 100% protection cannot be guaranteed.

† Sanofi & AstraZeneca are collaborating on the development and commercialization of Beyfortus[®].

What is RSV?

Respiratory syncytial virus (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.

Mild symptoms may include a runny nose, sneezing, and coughing, while severe symptoms can include wheezing and difficulty breathing.

Bronchiolitis (bron-key-oh-lie-tis)

is a viral infection in the smallest airways in the lungs (bronchioles). When the bronchioles swell and become inflamed, mucus may build up, leading to congestion and difficulty breathing. **Most cases of bronchiolitis are caused by RSV.**

Pneumonia (noo-mohn-yuh)

is a lung infection that can cause mild to severe coughing, fever, and trouble breathing.

How does RSV spread?

RSV spreads when droplets from a cough, sneeze, or infected surface get inside the eyes, nose, or mouth.



The best time to learn about RSV is before your baby does.

RSV season

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.

Who is at risk?



Severe RSV disease has the potential to hospitalize infants, including those who are healthy and born at term in their first season, as well as those born prematurely or with underlying health conditions.

A study with data gathered from 4 sites in the US between October 2014 and April 2015 demonstrated that 67% of children under 2 years of age who were hospitalized due to RSV had no reported underlying health condition.*



RSV infections can go from mild to severe in a few days, and severe illness can lead to hospitalization.



While most RSV cases are mild, it is not possible to predict which healthy infants could get seriously ill and end up in hospital.

* Based on a US study, with data of 1554 RSV-associated hospitalizations in children aged <2 years gathered from 4 Influenza Hospitalization Surveillance Network (FluSurv-NET) sites (California, Georgia, Minnesota, and Oregon) between October 2014 and April 2015.

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.

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.

How is Beyfortus[®] administered?



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.



Beyfortus[®] may be given at the same time as other vaccines during the same visit.

Do not use Beyfortus[®] if:



your child is allergic to nirsevimab or any of the other ingredients of this medicine. 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), have a bleeding problem or bruise easily, or are taking an anticoagulant medicine (to prevent blood clots).

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.

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.

Possible side effects

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 (e.g., redness, swelling, and pain where the injection is given)



Fever

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.

If you want more information about Beyfortus® or RSV:



Talk to your child's healthcare professional



Visit [KnowingRSV.ca](https://www.knowingRSV.ca) - a website for parents and caregivers

You can also find the full product monograph, which is prepared for healthcare professionals and includes the complete Patient Medication Information, by visiting the manufacturer's website:

<https://www.sanofi.ca/dam/jcr:a725a658-dc83-438a-892d-7b1fad114940/beyfortus.pdf>; by calling 1-800-265-7927; or by scanning the QR code.



Questions for your doctor



To help you have an informed discussion with your infant's doctor about RSV and protection with Beyfortus®, here are some questions worth asking:

- What are steps I can take to help limit the spread of RSV?
- Is there a way to predict whether my infant's RSV infection will be mild or serious?
- How can Beyfortus® help protect my infant from RSV?

sanofi

Copyright 2024 © Sanofi Pasteur Limited.
All rights reserved.
MAT-CA-2400888E-v1.0-07/2024
Do not use this piece after 30/06/2025
as some of the information may be outdated.



MEMBER OF
INNOVATIVE MEDICINES CANADA



Beyfortus®
(nirsevimab)