



Beyfortus[®] | 50 mg
(nirsevimab-alip) | 100 mg
Injection

An extra layer of protection against serious lung infection caused by Respiratory Syncytial Virus (RSV) when your baby needs it most.

Indication: Beyfortus is a prescription medicine used to help prevent a serious lung disease caused by Respiratory Syncytial Virus (RSV) in:

- Newborns and babies under 1 year of age born during or entering their first RSV season.
- Children up to 24 months of age who remain at risk of severe RSV disease through their second RSV season.

IMPORTANT SAFETY INFORMATION

Your child should not take Beyfortus if your child has a history of serious allergic reactions to nirsevimab-alip or any of the ingredients in Beyfortus.

Please see Important Safety Information throughout this brochure, and the full Prescribing Information including the Patient Information for more details.

What is RSV?

Respiratory Syncytial Virus (RSV) is a highly contagious virus that can lead to respiratory infection in babies. RSV is most common and spreads most often during the winter virus season (fall through spring) but can vary by local area. It can be spread from a kiss or by snuggling a favorite toy.



The facts and figures

- +** Most of the time RSV will cause a mild, cold-like illness. Initial symptoms of RSV can include:
 - congestion
 - runny nose
 - irritability
 - decreased appetite
 - fever
- +** As the infection spreads to the lungs the symptoms can worsen and can also cause severe illness such as bronchiolitis or pneumonia. Symptoms can include:
 - short, shallow, and abnormally fast breathing
 - a wheezing cough
 - nasal flaring
 - poor feeding
 - unusual tiredness
 - developing a blue tint to their lips or fingernails
 - fever
- +** RSV is unpredictable; it's hard to know if a baby will have a mild or serious infection—even if they're born healthy and at full term.
- +** Although severe RSV is rare, RSV is the leading cause of hospitalizations in babies under 1.
- +** Babies are 16x more likely to be hospitalized with RSV than with the flu.

Meet

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Beyfortus is an injection that is given directly to your baby to provide fast-acting protection against serious lung infection caused by RSV. Beyfortus can help prevent serious RSV lung infections for newborns and babies born during or entering their first RSV season.

Beyfortus is not a vaccine. It's a **preventative antibody** that gives babies the RSV antibodies they lack. A single dose gives your baby 5 months of protection against serious RSV lung infection.

An additional dose of Beyfortus may be needed for children up to 24 months of age who remain at increased risk for severe RSV disease in their second RSV season. For children undergoing cardiac surgery with cardiopulmonary bypass, an additional dose of Beyfortus is recommended as soon as the child is stable after surgery. Beyfortus may not protect all children.

Important Safety Information (cont'd):

Before your child receives Beyfortus, tell your healthcare provider about all of your child's medical conditions, including if your child:

- has ever had a reaction to Beyfortus.
- has bleeding or bruising problems. If your child has a problem with bleeding or bruises easily, an injection could cause a problem.

Please see Important Safety Information throughout this brochure, and the full [Prescribing Information](#) including the Patient information for more details.



When can my baby get Beyfortus?

Beyfortus should be given before the start of your baby's first RSV season, so they are protected before coming in contact with someone infected with RSV. The typical RSV season usually occurs from fall through spring. Your baby's doctor can tell you when the RSV season starts in your area.



If a baby is born during RSV season:

- Beyfortus should be given at birth.
- If not given in the hospital, they should receive it at their first doctor's visit.



If a baby is born in the spring or summer:

- Your baby can get Beyfortus at a regular checkup, just before RSV season.
- They can get their injection at the same time as other routine childhood vaccines.

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What are antibodies?

- Antibodies are made by your immune system. They're important, because they're the body's way of fighting off infections and helping to protect against serious illness.
- Antibodies, like monoclonal antibodies, can also be used as a therapy for certain conditions.
- The first monoclonal antibody was FDA approved for treatment in people in 1986 and technology has dramatically evolved over the past few decades.

What are preventative antibodies?

- A baby's immune system may not have the antibodies needed to protect them against their first infection. For over 20 years now, a preventative antibody, a type of monoclonal antibody, has been used in vulnerable babies.
- The preventative antibody in Beyfortus works like the antibodies your baby already makes but doesn't have enough of to help fight off RSV lung infection.
- Beyfortus can provide your baby with an extra layer of protection against serious RSV lung infection while their immune system is maturing. And it can start working within days.

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Important Safety Information (cont'd):

Tell your healthcare provider about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your infant should not receive a medicine called palivizumab if they have already received Beyfortus in the same RSV season.

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What makes **Beyfortus**[®] (nirsevimab-alip) | 50 mg 100 mg Injection **different?**

Beyfortus gives your baby an extra layer of immune protection against serious RSV lung infection. It's the right protection at the right time, especially since it is unknown when RSV can take a sudden turn.



Beyfortus is an injection of preventative antibodies.

It was created to provide an extra layer of protection against RSV which can be timed to the RSV season. Beyfortus is not a vaccine (which teaches the immune system to make its own antibodies). Beyfortus gives your baby the preventative antibodies to boost their immature immune system to help prevent serious RSV lung infection.



Beyfortus is recommended for newborns and babies born during or entering their first RSV season.

Beyfortus was studied in a wide range of babies, including healthy babies born at term, premature babies, and those with underlying health conditions. Beyfortus is the first preventative antibody of its kind.



Beyfortus helps protect against serious lung infection caused by RSV which may require medical care.

Medical care can include trips to the doctor, urgent care, ER, or hospital.



What are the potential side effects of Beyfortus?

In clinical trials, the safety of Beyfortus was shown to be similar to placebo. The most common side effects of Beyfortus include rash and pain, swelling, or hardness at the site of your baby's injection.

Placebo = any substance that has no active effects

How was Beyfortus developed?

- Physicians and scientists have been trying to develop a prevention for RSV disease for almost 60 years.
- The development of Beyfortus was nearly 7 years in the making with the first major clinical trial in babies in 2016.

Important Safety Information (cont'd):

Serious allergic reactions have happened with Beyfortus. Get medical help right away if your child has any of the following signs or symptoms of a serious allergic reaction:

- swelling of the face, mouth, or tongue
- difficulty swallowing or breathing
- unresponsiveness
- bluish color of skin, lips, or under fingernails
- muscle weakness
- severe rash, hives, or itching

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**Ask your baby's doctor
about Beyfortus.**

Before RSV.

Important Safety Information (cont'd):

The most common side effects of Beyfortus include rash and pain, swelling, or hardness at the site of your child's injection. These are not all the possible side effects of Beyfortus. Call your healthcare provider if you have questions about side effects.

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What is Beyfortus?

Beyfortus is an injection given directly to your baby that provides fast-acting protection against serious RSV lung infection. Beyfortus is recommended for newborns and babies born during or entering their first RSV season.

How does Beyfortus work?

Beyfortus is not a vaccine. It's a **preventative antibody** that gives babies the RSV antibodies they lack due to their immature immune system. It gives your baby an extra layer of protection against serious RSV lung infection when they need it most. Beyfortus gives your baby 5 months of protection against RSV.

What should I know about Beyfortus development?

The development of Beyfortus was nearly 7 years in the making with the first major clinical trial in babies in 2016.

What should I know about Beyfortus safety?

In clinical trials, the safety profile of Beyfortus was shown to be similar to placebo. The most common side effects of Beyfortus include rash and pain, swelling, or hardness at the site of your child's injection. Serious allergic reactions have happened with Beyfortus.

Get medical help right away if your child has any of the following signs or symptoms of a serious allergic reaction:

- Swelling of the face, mouth, or tongue
- Difficulty swallowing or breathing
- Unresponsiveness
- Bluish color of skin, lips, or under fingernails
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