



ALL BABIES ARE NOT THE SAME

Protecting your vulnerable baby from severe RSV disease

INDICATION

SYNAGIS, 50 mg and 100 mg for injection, is a prescription medication that is used to help prevent a serious lung disease caused by respiratory syncytial virus (RSV) in children:

- born prematurely (at or before 35 weeks) **and** who are 6 months of age or less at the beginning of RSV season
- who have a chronic lung condition, called bronchopulmonary dysplasia (BPD), that needed medical treatment within the last 6 months, **and** who are 24 months of age or less at the beginning of RSV season
- born with certain types of heart disease **and** who are 24 months of age or less at the beginning of RSV season

RSV=respiratory syncytial virus.

Please see additional Important Safety Information throughout and on page 11. Please see full [Prescribing Information](#) for SYNAGIS, including Patient Information.

SYNAGIS contains man-made, disease-fighting proteins called antibodies. It is not known if SYNAGIS is safe and effective to *treat* the symptoms of RSV in a child who already has RSV. SYNAGIS is used to help *prevent* RSV disease. It is not known if SYNAGIS is safe and effective in children who are older than 24 months of age at the start of dosing.

IMPORTANT SAFETY INFORMATION

Who should not receive SYNAGIS?

Children should not receive SYNAGIS if they have ever had a severe allergic reaction to it. Signs and symptoms of a severe allergic reaction could include severe rash, hives, or itchy skin;

swelling of the lips, tongue, or face; swelling of the throat, difficulty swallowing; difficult, rapid, or irregular breathing; bluish color of skin, lips, or under fingernails; muscle weakness or floppiness; unresponsiveness.

If your child has any of these signs or symptoms of a severe allergic reaction after getting SYNAGIS, call your child's healthcare provider or get medical help right away.



25+ YEARS OF PROTECTING THE MOST VULNERABLE BABIES FROM RSV



SEVERE RSV DISEASE

RSV SEASON

THE MOST VULNERABLE BABIES

SIGNS AND SYMPTOMS

HOW DOES RSV SPREAD?

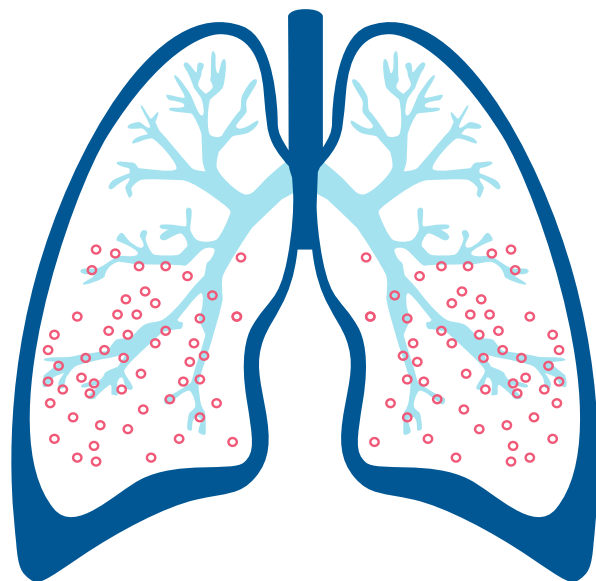
TIPS TO PROTECT YOUR BABY

SYNAGIS®

IMPORTANT SAFETY INFORMATION

HOW CAN **severe RSV disease affect your baby?**

RSV, or respiratory syncytial virus, is a seasonal virus that affects the lungs. Most children get it before their second birthday. For many children, RSV disease is mild, like a common cold. **But for the most vulnerable babies, RSV can cause severe disease.**



**As RSV moves lower in the lungs,
it can lead to serious lung infection.**

IMPORTANT SAFETY INFORMATION (continued)

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

- has ever had a reaction to SYNAGIS
- has bleeding or bruising problems

SYNAGIS is given by injection. If your child has a problem with bleeding or bruises easily, an injection could cause a problem.

Please see additional Important Safety Information throughout and on page 11.
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WHEN IS THE TYPICAL RSV season?

Like the flu, RSV is seasonal. That means your baby is more likely to catch the virus during certain times of the year.

RSV season usually runs from late fall through the spring, but it varies in different areas and from year to year.*

Most common RSV season



**Your baby could catch RSV at any time of year.
Ask your baby's doctor when RSV season happens in your area.**

*A baby may receive 5 or more monthly doses of SYNAGIS® during the RSV season. RSV seasonal onset and duration can vary by year and geographic region. Year-round activity has been reported in Florida and Puerto Rico.



The most vulnerable babies are more likely to be admitted to the hospital for severe RSV disease.

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IMPORTANT SAFETY INFORMATION (continued)

Tell your child's healthcare provider about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



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WHO ARE **the most vulnerable babies?**



Preemies

Premature babies (born at 35 weeks or less) who are 6 months of age or younger at the start of RSV season



Babies with lung issues

Babies with a chronic lung condition known as BPD (bronchopulmonary dysplasia) who are 24 months of age or younger at the start of RSV season



Babies with heart issues

Babies with a heart condition known as HS-CHD (hemodynamically significant congenital heart disease) who are 24 months of age or younger at the start of RSV season

IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of SYNAGIS?

Serious side effects include severe allergic reactions, which may happen after **any injection** of SYNAGIS and may be life-threatening or cause death. Call your child's healthcare provider or get medical help right away if your child has any of the signs or symptoms of a serious allergic reaction. See **"Who should not receive SYNAGIS?"** for more information.

Please see additional Important Safety Information throughout and on page 11.
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WHAT ARE THE SIGNS AND SYMPTOMS OF SEVERE **RSV** disease?



Coughing or wheezing



Fast, shallow breathing



Chest sinking in when breathing



Nostrils spreading out when breathing



Bluish lips or fingernails



Fever



IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of SYNAGIS? (continued)

The most common side effects of SYNAGIS include fever and rash.

These are not all the possible side effects for SYNAGIS. For more information ask your child's healthcare provider.



RSV may be mild when it starts, but it can become more severe after just a few days.

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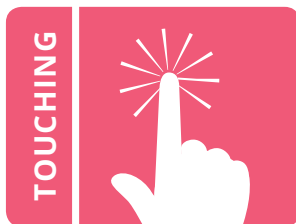
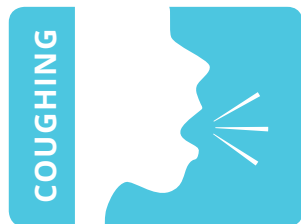
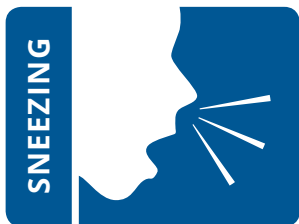
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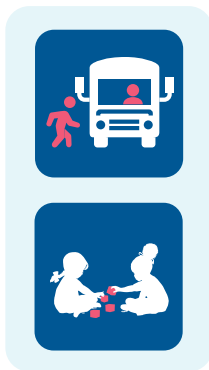
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HOW DOES RSV spread?

Just like the flu, RSV is highly contagious. It can spread to your baby easily.

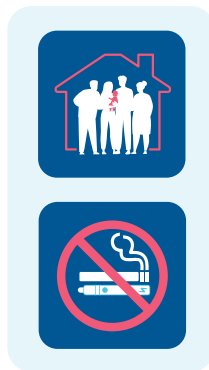


Your baby may be at higher risk for RSV disease if he or she:



Has preschool- or school-aged siblings

Attends a daycare center



Spends time in crowded places

Is around smoking or other pollution

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IMPORTANT SAFETY INFORMATION (continued)

Who should not receive SYNAGIS?

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If your child has any of these signs or symptoms of a severe allergic reaction after getting SYNAGIS, call your child's healthcare provider or get medical help right away.



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4 EASY TIPS TO **protect your baby**



Wash your hands



Wash your baby's things often



Keep your baby away from crowds and young children



Don't let anyone smoke near your baby



It is important to talk with your baby's doctor or nurse so they can make sure your baby gets the protection he or she needs.

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IMPORTANT SAFETY INFORMATION (continued)

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

- has ever had a reaction to SYNAGIS
- has bleeding or bruising problems



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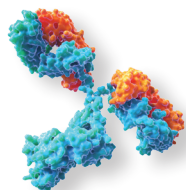
HOW CAN **SYNAGIS**[®] protect your vulnerable baby?



SYNAGIS starts working right away to protect your baby's lungs from severe RSV disease. Every SYNAGIS dose gives your baby RSV-blocking antibodies.

SYNAGIS has protected the most vulnerable babies from severe RSV disease for 25+ years

WHY ARE **antibodies** so important?



Antibodies are a key part of the immune system. Your body makes them to help protect you and your baby against infections such as viruses and bacteria.

Each SYNAGIS dose has enough antibodies to protect your baby from severe RSV disease for 28 to 30 days

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IMPORTANT SAFETY INFORMATION (continued)

SYNAGIS is given by injection. If your child has a problem with bleeding or bruises easily, an injection could cause a problem.



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PREMATURE INFANTS **get fewer antibodies than full-term infants.**

When you're pregnant, you pass antibodies to your baby. These antibodies give your baby protection against infection.

Babies get most of their antibodies during the last few weeks of a full-term pregnancy. **So your vulnerable baby may not have enough antibodies to fight off infections like RSV.**



Premature babies may have **ONLY HALF** the antibodies of full-term babies



Babies born at 28 to 33 weeks

50%
ANTIBODIES



Babies born at 37 to 40 weeks

100%
ANTIBODIES

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HOW OFTEN SHOULD **your baby** receive SYNAGIS®?

Your vulnerable baby may not have enough RSV-blocking antibodies.
Regular monthly SYNAGIS doses can protect your baby.

DOSE
MONTHLY

As your baby grows, your doctor will adjust the SYNAGIS dose.

Each month, your baby will get the right dose for their weight.

Each SYNAGIS dose has enough antibodies to protect your baby from severe RSV disease for 28 to 30 days.

HOW EFFECTIVE IS SYNAGIS®?



SYNAGIS reduced the number of vulnerable babies with RSV who had to be admitted to the hospital*

When premature babies or children with a lung condition called BPD received SYNAGIS, they were admitted to the hospital 55% less often than similar babies who did not receive SYNAGIS. When children with a heart condition called HS-CHD received SYNAGIS, they were admitted to the hospital 45% less often than similar babies who did not receive SYNAGIS.

*Compared with babies who did not receive SYNAGIS.



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IMPORTANT SAFETY INFORMATION (continued)

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The most common side effects of SYNAGIS include fever and rash.

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To report suspected adverse reactions, contact Sobi North America at 1-866-773-5274 or the FDA at 1-800-FDA-1088.

All imagery is for illustrative purposes only.



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