Help prevent severe RSV disease from turning a welcome home into a welcome back to the hospital



APPROVED USE FOR SYNAGIS

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 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
- in children who are older than 24 months of age at the start of dosing





Nobody wants to think their baby is at high risk for a **severe disease**

However, you should know that some children face a high risk of severe RSV disease.

Learning more is a great first step to protecting your baby. In this brochure, you'll find information on:

- The basics of severe RSV disease
- Who is considered a high-risk baby
- SYNAGIS—a prescription medication to help prevent severe RSV disease

Let's get started!



Talk to your health care provider if you have any questions about SYNAGIS or your baby's health

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 itchy rash; swelling of the face; difficulty swallowing; difficulty breathing; bluish color of the skin; muscle weakness or floppiness; and/or 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.

What is **severe RSV disease**?

RSV, or respiratory syncytial virus, is a seasonal virus that most children get by age 2. It often seems like a baby has a common cold, but for babies with certain health conditions, RSV can be very serious.



In high-risk babies, RSV can cause severe disease and lead to a serious lung infection, including:

Bronchiolitis (swelling of the lower airways in the lungs)

Pneumonia

IMPORTANT SAFETY INFORMATION (continued)

How is SYNAGIS given?

SYNAGIS is given as a monthly injection, usually in the thigh (leg) muscle, by your child's healthcare provider. If your child has a problem with bleeding or bruises easily, an injection could cause a problem.

Who is considered a **high-risk** baby?

Babies considered to be at high risk for severe RSV disease are:



Preemies

Infants who are born prematurely (at 35 weeks or less) and who are 6 months of age or younger at the start of RSV season



Babies with lung issues

Infants who have a chronic lung condition known as BPD/CLDP (bronchopulmonary dysplasia/chronic lung disease of prematurity) that required medical treatment within the previous 6 months, and who are 24 months of age or younger at the start of RSV season



Babies with heart issues

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



High-risk children are more likely to be admitted to the hospital for severe RSV disease.

How does **RSV spread**?

Just like the flu, RSV is spread easily. Your child can catch RSV through:



What increases the risk of getting RSV?

Certain situations can increase the risk of spreading and catching RSV. For example, attending daycare or living with preschool-aged children are both considered risk factors.

IMPORTANT SAFETY INFORMATION (continued)

Your child should receive their first injection of SYNAGIS before the RSV season starts, to help protect them before RSV becomes active. RSV season is usually fall through spring, but it may begin earlier or last longer in certain areas. When RSV is most active, your child will need to receive injections of SYNAGIS every 28-30 days to help protect them from severe RSV disease for about a month. Your child should continue to receive monthly injections of SYNAGIS until the end of RSV season. Your child may still get severe RSV disease after receiving SYNAGIS. If your child has an RSV infection, they should continue to get their monthly injections throughout the RSV season to help prevent severe disease from new RSV infections.

Tips to help prevent the **spread of RSV**



Wash your hands thoroughly before touching your baby and ask others to do the same



Don't let anyone smoke in your home or near your baby



Wash your baby's toys, clothes, and bedding often



Keep your baby away from crowds, young children, and people with colds





It is important to let your health care provider know if your daycare situation changes. This will help them consider the risk factors and make sure your child gets the protection he or she needs.

When is **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 from year to year and in different parts of the country. For example, RSV activity can happen year round in Florida and Puerto Rico.

Most common RSV season



Ask your health care provider when RSV season occurs in your area.

IMPORTANT SAFETY INFORMATION (continued)

The effectiveness of injections of SYNAGIS given less than monthly throughout the RSV season has not been established.

What are the signs and symptoms of **RSV disease**?



Coughing or wheezing that doesn't stop



Fast or troubled breathing



A fever, especially if it is greater than 100.4°F (rectal) in infants under 3 months of age



A bluish color around the mouth or fingernails



Flared nostrils and/or increased chest retractions when trying to breathe





There is no way to completely eliminate the risk for severe RSV disease, but there are ways to help prevent it.

How can SYNAGIS help protect your high-risk baby?

SYNAGIS is an injection that can help prevent severe RSV disease. It is not a vaccine, so it needs to be given each month. Every time your baby gets a SYNAGIS injection, he or she will receive a dose of virus-fighting antibodies, to help protect them from severe RSV disease.

What are antibodies?

- Antibodies are made by your body to fight infections. They are an important part of the immune system
 - Certain high-risk infants are not able to produce enough antibodies to provide long-term protection from an RSV infection
- During pregnancy, antibodies are passed from a mother to her baby
 - Premature infants get fewer antibodies from the mother compared to full-term infants
- In the months after birth, the amount of these antibodies decreases. With fewer antibodies to protect them, it gets harder for some infants to fight serious infections



SYNAGIS can help protect your baby from severe RSV disease.

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.



SYNAGIS antibody attaches to RSV to help prevent infection.

How often should your high-risk baby receive SYNAGIS?

Each dose of SYNAGIS provides RSV-fighting antibodies to protect your baby for about a month.

- Since high-risk babies may not have enough antibodies, regular monthly SYNAGIS doses can help
- If your baby was considered high risk and born during RSV season, he or she may have received the first dose of SYNAGIS in the hospital. During RSV season, babies who are at high risk should continue to get SYNAGIS every 28 to 30 days after they leave the hospital

It's important for high-risk babies to get every SYNAGIS injection on time during RSV season.

There is no information on how effective SYNAGIS will be if it is not given monthly during the entire RSV season.



Your baby should get a dose of SYNAGIS every 28 to 30 days during RSV season.

IMPORTANT SAFETY INFORMATION (continued)

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.

Common side effects of SYNAGIS include fever and rash. These are not all the possible side effects of SYNAGIS.



How effective is **SYNAGIS**?



Scientists found that high-risk children who received SYNAGIS had half the risk of hospitalization from RSV compared to those who did not receive SYNAGIS.

High-risk children include premature infants born 35 weeks or earlier, and children 24 months of age or younger with BPD/CLDP or HS-CHD.

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Please see full Prescribing Information for SYNAGIS, including Patient Information.





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