Learn more about why severe RSV disease can turn a welcome home into a welcome back to the hospital.

APPROVED USE
SYNAGIS® (palivizumab) 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

Children should not receive SYNAGIS if they have ever had a severe allergic reaction to it.

Please see additional Important Safety Information on pages 22-24 and accompanying full Prescribing Information, including Patient Information.
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The words “high risk” can seem scary

Especially when it comes to your baby. But for certain children, there is a high risk of severe RSV disease.

Learning more is a great first step. This brochure can help you do that. You’ll find information on:

- The basics of severe RSV disease
- Who is considered a high-risk child
- Preventive therapy with SYNAGIS® (palivizumab)
- Available programs that can help support you through the RSV season

Let’s get started.

Important Safety Information

Serious side effects include severe allergic reactions, which may happen after any injection of SYNAGIS and may be life-threatening or cause death.
Respiratory syncytial virus, or RSV, is a very common virus that most children will catch by 2 years of age.

Severe RSV disease is caused by this widespread virus and can lead to a serious lung infection. A serious lung infection may include:

- Bronchiolitis (swelling of the lower airways of the lungs)
- Pneumonia

Please see additional Important Safety Information on pages 22-24 and accompanying full Prescribing Information, including Patient Information.
How does RSV spread?
Just like the flu, RSV is spread easily. Your child can be put at risk of catching RSV by things like:

- Sneezing
- Coughing
- Touching

What increases the risk of spreading RSV?
 Certain situations can increase the risk of spreading or catching RSV. For example, is your child often around other children? Being in crowded spaces is considered a risk factor.

**High-risk situations can include:**

- Attending daycare
- Living with preschool-aged siblings

It is important to let your doctor know if your daycare arrangements change. Your doctor needs to consider all risk factors to make sure that your child gets the protection he or she needs.

Talk to your doctor if you have any questions about SYNAGIS® (palivizumab) or your baby’s health.
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 starts in the fall and ends in the spring, but it varies in different parts of the country. For example, year-round RSV activity has been reported in Florida and Puerto Rico.

Most common RSV season

Ask your doctor when RSV season is where you live, or visit RSVAlert.com for more information.

Please see additional Important Safety Information on pages 22-24 and accompanying full Prescribing Information, including Patient Information.
What are the symptoms of RSV disease?

- Coughing and wheezing that do not stop
- Difficulty breathing
- A fever (a temperature over 100.4F rectal in infants under 3 months of age is cause for concern)

There is no cure for severe RSV disease, but there are ways to help prevent it.

Talk to your doctor if you have any questions about SYNAGIS® (palivizumab) or your baby’s health.
Who is considered a **high-risk** baby?

**Your child may be at high risk for severe RSV disease if he or she:**

1. Was premature (born early at 35 weeks or less) and who are 6 months of age or less at the beginning of RSV season.

2. Has certain types of chronic lung disease, referred to as bronchopulmonary dysplasia (BPD) or chronic lung disease of prematurity (CLDP), needed medical treatment within the last 6 months, and who are 24 months of age or less at the beginning of RSV season.

3. Was born with certain types of heart disease, referred to as congenital heart disease, or CHD and who are 24 months of age or less at the beginning of RSV season.

**Important Safety Information**

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.

Please see additional **Important Safety Information** on pages 22-24 and accompanying **full Prescribing Information**, including Patient Information.
These high-risk children are more likely to be admitted to the hospital for severe RSV disease than low-risk children.

Talk to your doctor if you have any questions about SYNAGIS® (palivizumab) or your baby’s health.
How can you help protect your high-risk baby?

SYNAGIS® (palivizumab) can help protect your high-risk baby from severe RSV disease. SYNAGIS is not a vaccine. It’s an FDA-approved injection of antibodies that is given monthly to help protect high-risk children from severe RSV disease.

What are antibodies?

- Antibodies are proteins that your body makes to fight infection. They are a very important part of the immune system.
- During pregnancy, antibodies are passed from mother to baby. These are called maternally transmitted antibodies.
- In the months after birth, the amount of these antibodies gets lower. With fewer antibodies to protect them, it is harder for some infants to fight off serious infections.

Please see additional Important Safety Information on pages 22-24 and accompanying full Prescribing Information, including Patient Information.
SYNAGIS contains virus-fighting antibodies that attach to a specific protein found on the surface of RSV. This can help protect your high-risk baby from severe RSV disease.

**Important Safety Information**

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.
How often should your high-risk baby receive SYNAGIS® (palivizumab)?

SYNAGIS is not a vaccine. Each dose provides enough antibodies to protect your baby for about a month.

- High-risk babies may not have enough antibodies to fight off an RSV infection. Regular monthly dosing with SYNAGIS can help.

- If your high-risk baby was born during RSV season, he or she may have received the first dose of SYNAGIS in the NICU. During RSV season, babies who are at high risk should continue getting SYNAGIS every 28 to 30 days.

**DOSE EVERY**

28–30 DAYS

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

Please see additional Important Safety Information on pages 22-24 and accompanying full Prescribing Information, including Patient Information.
It’s important for high-risk babies to get every SYNAGIS injection on time during the entire RSV season. There is no information on how effective SYNAGIS will be if shots are given less than monthly during the entire RSV season.

Talk to your doctor if you have any questions about SYNAGIS or your baby’s health.

IMPORTANT SAFETY INFORMATION

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. 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.

The effectiveness of injections of SYNAGIS given less than monthly throughout the RSV season has not been established.
How effective is SYNAGIS® (palivizumab) for high-risk babies?

Clinical studies showed that high-risk children who received SYNAGIS were less likely to be hospitalized due to 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 CHD.
SYNAGIS 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

Talk to your doctor if you have any questions about SYNAGIS or your baby’s health.
Cradle with Care℠ is a SYNAGIS program that can help you through the RSV season. If you’re not sure what to do or when to do it, Cradle with Care can help.

Cradle with Care offers:

**SYNAGIS appointment and RSV season reminders.** We’ll send you alerts by mail, text, or e-mail when the season starts in your area and when your next SYNAGIS appointment is coming up.

**Educational information for your baby’s health.** You’ll receive tips for helping to protect against RSV, and information about your baby’s specific condition.

**Help with financial and insurance matters.** We’ll show you where to go to get the support you need.

Please see additional Important Safety Information on pages 22-24 and accompanying full Prescribing Information, including Patient Information.
How do you enroll in Cradle with Care?

The first step to getting the support you need is to sign up. There are 3 ways to enroll.

**With your doctor**
- You may have already filled out the paperwork with your doctor—either in the doctor’s office or while you were still in the hospital

**Through the mail**
- Fill out the attached card and mail it back to us. We’ll take care of the rest

**On our website**
- Visit CradleWithCare.com, and fill out your patient profile. Hit submit and you’re enrolled!

Talk to your doctor if you have any questions about SYNAGIS or your baby’s health

**IMPORTANT SAFETY INFORMATION**

Common side effects of SYNAGIS include fever and rash.
We want your baby to have the best possible start. **The Cradle with Care™ program** can help you through the dosing process for SYNAGIS so you can focus on what matters most: your child.

By enrolling in the program, you’ll receive:

- **A Welcome Kit**, which includes a 12-month calendar, stickers to mark important dates, quick reference cards about RSV, and a rubber stroller tag to remind others to wash their hands before touching your baby.

- **Protection Tips**, with everyday things you can do to help protect your high-risk baby.

- **Condition-specific Materials**, with information focused on your baby’s health needs.

Please see additional Important Safety Information on pages 22-24 and accompanying full Prescribing Information, including Patient Information.
We know that it’s a lot of information to take in. That’s why we leave it up to you how you want to receive it. Whether you prefer mail, e-mail, and/or text, we’ll help you stay connected and informed throughout RSV season.

- **RSV Season Start Reminders**, to let you know RSV season may be starting in your area soon
- **Appointment Reminders**, to alert you when your baby’s next SYNAGIS dose is scheduled
- **End of Season Reminder**, to let you know that the RSV season is almost over. You’ll also get a survey about the program so you can help us keep improving Cradle with Care for future parents and caregivers
- **Financial Assistance**, which gives you a place to go for help with financial and insurance matters

Talk to your doctor if you have any questions about SYNAGIS or your baby’s health.

**IMPORTANT SAFETY INFORMATION**

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.
Where can you find support?

There is help to get the SYNAGIS doses your baby needs.

AstraZeneca, the maker of SYNAGIS, offers the Access 360 program. Access 360 provides coverage support and connects you with affordability programs. Think of it as a support system, there to help you with financial and coverage barriers. To learn more about support that may be available for you, call us Mon-Fri, 8 AM – 8 PM ET at 1-844-ASK-A360 (1-844-275-2360) to speak with one of our Patient Access Specialists who are ready to help you.

Enrolling in Access 360 is easy. Fill out the attached form (the same one you’ll use to sign up for the Cradle with Care™ program), sign it, and mail it in.

Please see additional Important Safety Information on pages 22-24 and accompanying full Prescribing Information, including Patient Information.
Here are a few examples of how Access 360 can help you:

- Access 360 can work with your healthcare provider to help identify your coverage and out-of-pocket costs for AstraZeneca medications
- Our Patient Access Specialists can also connect you with affordability programs to address financial barriers. Our patient programs are designed to help patients who have no insurance or are denied access to appropriate medicine, as well as those patients with high out-of-pocket costs
- At any point along your treatment journey you can call us to see how we can help you access and afford AstraZeneca medicines

For more information, visit MyAccess360.com
Or call 1-844-275-2360 to speak to a specialist.

Talk to your doctor if you have any questions about SYNAGIS or your baby’s health.

IMPORTANT SAFETY INFORMATION
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
Important Safety Information

Who should not receive SYNAGIS® (palivizumab)?

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.
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. 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.

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

Common side effects of SYNAGIS include fever and rash.

These are not all the possible side effects of SYNAGIS.

Please see accompanying full Prescribing Information, including Patient Information.
Registration card for Cradle with Care™ and Access 360™

Asterisk (*) indicates a required field.

Patient Information

*Patient’s name: ____________________________

*Birth date: ____________________________

Month / Day / Year

At the start of RSV season, your high-risk child (check all that apply):

- [ ] was born prematurely at ________ weeks gestational age and who are 6 months of age or less
- [ ] has bronchopulmonary dysplasia/chronic lung disease of prematurity (BPD/CLDP), that needed medical treatment within the last 6 months and who are 24 months of age or less
- [ ] has congenital heart disease (CHD) and who are 24 months of age or less

Was SYNAGIS® (palivizumab) prescribed?  YES  NO  If yes, how many?

Received a dose?  YES  NO  Date of last dose: ________ / ________ / ________  Date of next scheduled dose: ________ / ________ / ________

Please see Important Safety Information on back cover of brochure.

Parent/Caregiver Contact Information

For parent/caregiver information, fill out Name and at least one of the following: Mobile phone, E-mail, or Address.

*Full name: ____________________________

*Mobile phone #: ____________________________  Home phone #: ____________________________

By entering your mobile phone number, you agree to enter into the Cradle with Care Mobile Program to receive no more than 2 messages a month. Once you sign up, you can expect to receive a confirmation text from 47146 to the mobile number provided above requesting your confirmation of enrollment. Text message rates may apply.

*Mailing address:

Street: ____________________________

City: ____________________________  State: ____________________________  ZIP code: ____________________________

*Email address: ____________________________

Pediatrician/Specialist: ____________________________

Name: ____________________________  Phone: ____________________________  Fax: ____________________________

Ped/Spec address:

Street: ____________________________  suite: ____________________________  city: ____________________________  State: ____________________________  ZIP code: ____________________________

Preferred language: [ ] English  [ ] Spanish

NOTE: To send you information and updates from Cradle with Care™, we need to have your signature on file.

Access 360™ Patient Authorization: Fax to 1-844-329-2360 if signed below

By signing below, I agree to the use and disclosure of the patient’s PHI and who may see it for the purposes described in the “Access 360” section of the previous page. If I cancel this Authorization, the Healthcare Providers and Insurers are prohibited from further disclosing the patient’s PHI to AstraZeneca, including its contractors and affiliates; however, it will not impact AstraZeneca’s ability to use and disclose PHI already received prior to the receipt of the revocation. If I refuse to sign this Authorization, or revoke it later, the patient will not be able to receive assistance from Access 360 Programs. I may cancel my authorization at any time by sending written notification of my withdrawal to: Access 360 Program, One AstraZeneca Way, Gaithersburg, MD 20878; faxing written notification to Access 360 at 1-844-329-2360, or by calling Access 360 at 1-844-275-2360. Once the recipient receives the patient’s PHI, it may be redisclosed by the recipient and may no longer be protected by federal privacy laws.

*Signature of Parent/Caregiver: ____________________________  Date: ____________________________

This authorization expires two (2) years from the date I sign this form unless a shorter period is required by state law.

Cradle with Care™: Fax to 1-844-329-2360 if signed below

By signing below, I am allowing the Hospital and my child’s healthcare providers to give my child’s information to AstraZeneca and its contractors for the purposes described in the “Cradle with Care” section on the previous page. At any time, I can change my mind and I no longer want my child’s doctors to tell my child’s information to AstraZeneca or its contractors. I may cancel my authorization at any time by sending written notification of my withdrawal to: AstraZeneca, P.O. Box 4713, Trenton, NJ 08650-8908, or by faxing written notification to 1-844-329-2360. However, if my child’s information was already given to AstraZeneca before a letter was received, then my child’s doctors/Hospital will not ask AstraZeneca to give this information back. I understand that the Cradle with Care program can send me text messages if I provide my mobile number above and that text messaging rates may apply.

*Signature of Parent/Caregiver: ____________________________  Date: ____________________________

This authorization expires two (2) years from the date I sign this form unless a shorter period is required by state law.