Indication
Synagis® (palivizumab) is a prescription medication that is used to help prevent a serious lung disease caused by respiratory syncytial virus (RSV) in children at high risk for severe lung disease from RSV.

Select Safety Information
Common side effects of Synagis include fever and rash. Other possible side effects include skin reactions around the area where the shot was given (like redness, swelling, warmth, or discomfort).

Please see complete Important Safety Information on pages 22-24 and accompanying full Prescribing Information, including Patient Information.
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.

Select Safety Information
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What is severe RSV disease?

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

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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

FALL
WINTER
SPRING
SUMMER

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

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What are the symptoms of RSV disease?

- Coughing and wheezing that does not stop
- Difficulty breathing
- A fever (a temperature over 100.4°F 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:

- Was premature (born early at 35 weeks or less)
- Has certain types of chronic lung disease, referred to as bronchopulmonary dysplasia (BPD) or chronic lung disease of prematurity (CLDP)
- Was born with certain types of heart disease, referred to as congenital heart disease, or CHD

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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.
Synagis® (palivizumab) can help protect your high-risk baby from severe RSV disease. Synagis is not a vaccine. It’s an FDA-approved shot 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.

How can you help protect your high-risk baby?

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.

Select 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 flappiness; a drop in blood pressure; and/or unresponsiveness. If your child has any of these signs or symptoms of a severe allergic reaction after getting Synagis, be sure to tell your child’s healthcare provider or get medical help right away.
Talk to your doctor if you have any questions about Synagis or your baby’s health.

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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.

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

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It’s important for high-risk babies to get every Synagis shot 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.

Select Safety Information

Synagis is given as a shot, usually in the thigh muscle, each month during the RSV season. Your child should receive their first Synagis shot before the RSV season starts, to help protect them before RSV becomes active.

When RSV is most active, your child will need to receive Synagis shots every 28-30 days to help protect them from severe RSV disease for about a month. Your child should continue to receive monthly shots 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 shots throughout the RSV season to help prevent severe disease from new RSV infections.

The effectiveness of Synagis shots 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.

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Possible, serious side effects include severe allergic reaction, which may occur after any dose of Synagis. Such reactions may be life-threatening or cause death. Unusual bruising and/or groups of tiny red spots on the skin have also been reported.

Common side effects of Synagis include fever and rash. Other possible side effects include skin reactions around the area where the shot was given (like redness, swelling, warmth, or discomfort).

Talk to your doctor if you have any questions about Synagis or your baby’s health.
Where can you go for help?

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 email 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.

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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.

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What are the benefits of enrollment?

We want your baby to have the best possible start. The Cradle with Care™ program can help you through the Synagis® dosing process 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

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, email, 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.

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Where can you find financial assistance?

There is help for getting the Synagis® doses your baby needs. MedImmune, the maker of Synagis, offers the Access 360™ program. Access 360 is a free resource for parents, caregivers, and their doctors. Think of it as a support system, there to help you with financial and coverage barriers.

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.

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Here are a few examples of how Access 360 can help you:

- **Synagis Copay Savings Program**: For eligible patients, ask your doctor how Access 360 can help assist you with out-of-pocket costs for Synagis.
- **Patient Assistance through Non-profit (PANF)**: Access 360 can refer you to this organization to apply for grants that help with the cost of Synagis.
- **MedImmune Assistance Program (MAP)**: For eligible patients who are uninsured or uncovered by their insurance company, your doctor may suggest this Access 360 program to provide Synagis free of charge.

For more information, visit MyAccess360.com/patients. Or call 1-877-778-9010 to speak to a representative.

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

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What is Synagis® (palivizumab)?
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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 flappiness; a drop in blood pressure; and/or unresponsiveness. If your child has any of these signs or symptoms of a severe allergic reaction after getting Synagis, be sure to tell your child’s healthcare provider or get medical help right away.

How is Synagis given?
Synagis is given as a shot, usually in the thigh muscle, each month during the RSV season. Your child should receive their first Synagis shot before the RSV season starts, to help protect them before RSV becomes active. When RSV is most active, your child will need to receive Synagis shots every 28-30 days to help protect them from severe RSV disease for about a month. Your child should continue to receive monthly shots 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 shots throughout the RSV season to help prevent severe disease from new RSV infections.

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Please see additional Important Safety Information on back cover.
What are the side effects of Synagis®?
Possible, serious side effects include severe allergic reaction, which may occur after any dose of Synagis. Such reactions may be life-threatening or cause death. Unusual bruising and/or groups of tiny red spots on the skin have also been reported.

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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

High-risk child (check all that apply):
If you are unsure of your baby’s diagnosis, talk to your doctor.

☐ Prematurity: Born at ___________ weeks gestational age

☐ Bronchopulmonary dysplasia/chronic lung disease of prematurity (BPD/CLDP)

☐ Congenital heart disease (CHD)

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.

By entering your mobile phone number, you agree to enroll 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.
Parent/Caregiver Contact Information

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

*Full name: ____________________________________________________________

  First

  Last

*Mobile phone #: ____________________________  Home phone #: ____________________________

By entering your mobile phone number, you agree to enroll 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.

*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 MedImmune, including its contractors and affiliates; however, it will not impact MedImmune’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 MedImmune 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 MedImmune 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 decide I no longer want my child’s doctors to give my child’s information to MedImmune or its contractors. I may cancel my authorization at any time by sending written notification of my withdrawal to: MedImmune, P.O. Box 4715, Woburn, MA 01888-9955, or by faxing written notification to 1-844-329-2360. However, if my child’s information was already given to MedImmune before a letter was received, then my child’s doctors/Hospital will not ask MedImmune 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.