SIMPLIFIED STEPS TO SYNAGIS
Process Overview for a Patient Referral

1 Identify
- Identify patients at high risk for severe respiratory syncytial virus (RSV) disease
- Determine patient eligibility for SYNAGIS
- Consider patients who may be eligible for SYNAGIS during a 2nd RSV season

2 Educate Parents
- Educate parents on severe RSV disease and SYNAGIS
- Explain approval process and set expectations
- Have the parent review and sign the Patient Authorization Form (PAF)

3 Complete Referral
- Determine medical and pharmacy benefits
- Identify the specialty pharmacy that can service your patient
- Utilize the Access 360™ Benefit Investigation (Bl) if necessary
- Fill out correct referral form completely and accurately

4 Submit Referral
- Identify specialty pharmacy submission and payer authorization requirements; utilize Access 360™ services if necessary
- Refer to payer grid for specialty pharmacy submission
- Submit referral to appropriate party with supportive documentation
- Be sure to track referral to ensure dose is received in time for scheduled injection
- Utilize the Access 360™ Referral Follow-up if necessary

5 Approval or Denial
- Communicate approval or denial to parent
- If approved, parent will receive a consent-to-ship call from the specialty pharmacy
- On approval, coordinate delivery of product with specialty pharmacy and parents
- Access 360™ and your Field Reimbursement Manager (FRM) can provide insight into this process

6 Continuum of Care
- Ensure adherence to monthly dosing in season through:
  - Ongoing discussions with parents
  - Ongoing coordination with specialty pharmacy
- Manage insurance change in January if applicable

IMPORTANT SAFETY INFORMATION
SYNAGIS® (palivizumab) is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. Safety and efficacy were established in children with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (≤35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD). The recommended dose of SYNAGIS is 15 mg/kg of body weight given monthly by intramuscular injection. The first dose of SYNAGIS should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season. Children who develop an RSV infection should continue to receive monthly doses throughout the RSV season.

The efficacy of SYNAGIS at doses less than 15 mg/kg, or of dosing less frequently than monthly throughout the RSV season, has not been established.

Please see additional Important Safety Information on reverse side and accompanying full Prescribing Information.

QUESTIONS? Please see reverse side for helpful contact information.
CONTACT INFORMATION

AstraZeneca Representative
Name:
Phone:

For reports on RSV activity trends in your area
Go to the RSVAlert* website at:
www.rsvalert.com

Go to the Centers for Disease Control and Prevention National Respiratory and Enteric Virus Surveillance System website at:
www.cdc.gov/surveillance/nrevss/rsv/
Call AstraZeneca Information Center (AZIC) at: 1-800-236-9933

Online Resources
SYNAGIS® website: www.synagis.com

*RSVAlert® is a surveillance program that reports results of RSV tests (antigen, culture, and PCR) on a weekly basis at the national, state, and local levels.

IMPORTANT SAFETY INFORMATION (Continued)
SYNAGIS is contraindicated in children who have had a previous significant hypersensitivity reaction to SYNAGIS. Cases of anaphylaxis and anaphylactic shock, including fatal cases, have been reported following initial exposure or re-exposure to SYNAGIS. Other acute hypersensitivity reactions, which may be severe, have also been reported on initial exposure or re-exposure to SYNAGIS. The relationship between these reactions and the development of antibodies to SYNAGIS is unknown. If a significant hypersensitivity reaction occurs with SYNAGIS, its use should be permanently discontinued. If a mild hypersensitivity reaction occurs, clinical judgment should be used regarding cautious readministration of SYNAGIS. As with any intramuscular injection, SYNAGIS should be given with caution to children with thrombocytopenia or any coagulation disorder. Palivizumab may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays.

Adverse reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. In post-marketing reports, cases of severe thrombocytopenia (platelet count <50,000/microliter) and injection site reactions have been reported.

Please see accompanying full Prescribing Information for SYNAGIS, including Patient Information.
SYNAGIS® (palivizumab) injection, for intramuscular use

**INDICATIONS AND USE**

Synagis is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease.

- Safety and efficacy were established in children with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (less than or equal to 35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD).
- The safety and efficacy of Synagis have not been established for treatment of RSV disease.

**DOSAGE AND ADMINISTRATION**

15 mg per kg of body weight, administered intramuscularly prior to commencement of the RSV season and remaining doses administered monthly throughout the RSV season.

- Children undergoing cardio-pulmonary bypass should receive an additional dose of Synagis as soon as possible after the cardio-pulmonary bypass procedure (even if sooner than a month from the previous dose). Thereafter, doses should be administered monthly as scheduled. (2.1, 12.3)

**DOSE FORMS AND STRENGTHS**

Single-dose liquid solution vials: 50 mg per 0.5 mL and 100 mg per 1 mL. (3)

**WARNINGS AND PRECAUTIONS**

- **Hypersensitivity Reactions**: Reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. (6.1)
- **Coagulation Disorders**: Anaphylaxis and anaphylactic shock (including fatal cases), and other severe acute hypersensitivity reactions have been reported. If a significant hypersensitivity reaction occurs with Synagis, its use should be permanently discontinued. (5.1)
- **RSV Diagnostic Test Interference**: Palivizumab may interfere with immunological-based RSV diagnostic tests such as some antigen detection-based assays. (5.3, 12.4)

**ADVERSE REACTIONS**

- **Drug Interactions**: Using aseptic techniques, attach a sterile needle to a sterile syringe. Remove the flip top from the Synagis vial and wipe the rubber stopper with a disinfectant (e.g., 70% isopropyl alcohol). Insert the needle into the vial and withdraw into the syringe an appropriate volume of solution. Administer immediately after drawing the dose into the syringe. (7.1)
- **OVERDOSE**: Synagis should be administered in a dose of 15 mg per kg intramuscularly using aseptic technique, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve. The dose (volume of injection in mL) per month = patient weight (kg) x 15 mg per kg - 100 mg per mL of Synagis. Injection volumes over 1 mL should be given as a divided dose. Synagis is supplied as a single-dose vial and does not contain preservatives. Do not re-enter the vial after withdrawal of drug; discard unused portion. Only administer one dose per vial. (10.1, 14.4)
- **Infections**: Use sterile disposable syringes and needles. To prevent the transmission of hepatitis viruses or other infectious agents from one person to another, DO NOT reuse syringes and needles. (6.2)

**CONTRAINDICATIONS**

- Pre-existing significant hypersensitivity reaction to Synagis. (4)
- **Carcinogenesis, Mutagenesis, Impairment of Fertility**: Synagis is contraindicated in children who have had a previous significant hypersensitivity reaction to Synagis. (13.3)

**ADVERSE REACTIONS**

Adverse reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact MedImmune at 1-877-633-4411 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**USE IN SPECIFIC POPULATIONS**

Safety and effectiveness in children greater than 24 months of age at the start of dosing have not been established. (6.4)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

*Sections or subsections omitted from the full prescribing information are not listed.*

**FULL PRESCRIBING INFORMATION: CONTENTS**

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
   2.1 Dosing Information
   2.2 Administration Instructions
3 DOSE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
   5.1 Hypersensitivity Reactions
   5.2 Coagulation Disorders
   5.3 RSV Diagnostic Test Interference
   5.4 Treatment of RSV Disease
   5.5 Proper Administration
6 ADVERSE REACTIONS
   6.1 Clinical Studies Experience
   6.2 Postmarketing Experience
7 DRUG INTERACTIONS
8 USE IN SPECIFIC POPULATIONS
   8.1 Pregnancy
   8.4 Pediatric Use
10 OVERDOSE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
   12.1 Mechanism of Action
   12.3 Pharmacokinetics
   12.4 Microbiology
13 NONCLINICAL TOXICOLOGY
   13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
16 HOW SupPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

*Revised: 03/2014*
Palmivizumab may interfere with immunological-based RSV diagnostic tests such as some antigen detection-based assays. In addition, palmivizumab inhibits virus replication in cell culture, and therefore may also interfere with viral culture assays. Palmivizumab does not interfere with reverse transcriptase-polymerase chain reaction based assays. Assay interference could lead to false-negative RSV diagnostic test results. Therefore, diagnostic test results, when obtained, should be used in conjunction with clinical findings to guide medical decisions [see Microbiology (12.4)].

5.4 Treatment of RSV Disease

The safety and efficacy of Synagis have not been established for treatment of RSV disease.

5.5 Proper Administration

The single-dose vial of Synagis does not contain a preservative. Administration of Synagis should occur immediately after dose withdrawal from the vial. The vial should not be re-entered. Discard any unused portion.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to Synagis (n=1639) compared with placebo (n=1143) in children 3 days to 24.1 months of age at high risk of RSV-related hospitalization in two clinical trials. Trial 1 was conducted during a single RSV season and studied a total of 1502 children less than or equal to 24 months of age with BPD or infants with premature birth (less than or equal to 32 weeks gestation) who were less than or equal to 6 months of age at study entry. Trial 2 was conducted over four consecutive seasons among a total of 1287 children less than or equal to 24 months of age with hemodynamically significant congenital heart disease.

In Trials 1 and 2 combined, fever and rash were each reported more frequently among Synagis than placebo recipients, 27% versus 25%, and 12% versus 10%, respectively. Adverse reactions observed in the 153-patient crossover study comparing the liquid and lyophilized formulations were comparable for the two formulations, and were similar to those observed with Synagis in Trials 1 and 2.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post approval use of Synagis. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Blood and Lymphatic System Disorders: severe thrombocytopenia (platelet count less than 50,000 per microliter)

General Disorders and Administration Site Conditions: injection site reactions

Limited information from post-marketing reports suggests that, within a single RSV season, adverse events after a sixth or greater dose of Synagis are similar in character and frequency to those after the initial five doses.

7 DRUG INTERACTIONS

No formal drug-drug interaction studies were conducted. In Trial 1, the proportions of children in the placebo and Synagis groups who received routine childhood vaccines, influenza vaccine, bronchodilators, or corticosteroids were similar and no incremental increase in adverse reactions was observed among children receiving these agents.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Palmivizumab is not indicated for adult use. It is not known whether palmivizumab can cause fetal harm or could affect reproductive capacity when administered to a pregnant woman.

Animal Data

Animal reproduction studies have not been conducted.

8.4 Pediatric Use

The safety and effectiveness of Synagis in children greater than 24 months of age at the start of dosing have not been established.

10 OVERDOSAGE

Overdoses with doses up to 65 mg per kg have been reported in clinical studies and post-marketing experience with Synagis, and in some cases, adverse reactions were reported. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions and appropriate symptomatic treatment instituted.

11 DESCRIPTION

Palmivizumab is a humanized monoclonal antibody (IgG1xk) produced by recombinant DNA technology, directed to an epitope in the A antigenic site of the F protein of RSV. Palmivizumab is a composite of human (95%) and murine (5%) antibody sequences. The human heavy chain sequence was derived from the constant domains of human IgG1 and the variable framework regions of the VH genes Cα2 and Cε2. The human light chain sequence was derived from the constant domain of Cκ and the variable framework regions of the VL gene K104 with Jκ-4. The murine sequences were derived from a murine monoclonal antibody, Mab 1129, in a process that involved the grafting of the murine complementarity determining regions into the human antibody frameworks. Palmivizumab is composed of two heavy chains and two light chains and has a molecular weight of approximately 148,000 Daltons.

Synagis is supplied as a sterile, preservative-free liquid solution at 100 mg per mL to be administered by intramuscular injection. Thimerosal or other mercury-containing salts are not used in the production of Synagis. The solution has a pH of 6.0 and should appear clear or slightly opalescent.

Each 100 mg single-dose vial of Synagis liquid solution contains 100 mg of palmivizumab and also contains chloride (0.5 mg), glycine (0.1 mg), and histidine (3.9 mg), in a volume of 1 mL. Each 50 mg single-dose vial of Synagis liquid solution contains 50 mg of palmivizumab and also contains chloride (0.2 mg), glycine (0.06 mg), and histidine (1.9 mg), in a volume of 0.5 mL.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Palmivizumab is a recombinant humanized monoclonal antibody with anti-RSV activity [see Microbiology (12.4)].

12.3 Pharmacokinetics

In children less than or equal to 24 months of age without congenital heart disease (CHD), the mean half-life of palmivizumab was 20 days and monthly intramuscular doses of 15 mg per kg were achieved in children with a body weight of 10 kg 10 kg and with the trough serum concentrations of 37 ± 21 mcg per mL after the first injection, 57 ± 41 mcg per mL after the second injection, 68 ± 51 mcg per mL after the third injection, and 72 ± 50 mcg per mL after the fourth injection. Trough concentrations following the first and fourth Synagis dose were similar in children with CHD and in non-cardiac patients. In children given Synagis for a second season, the mean ± SD serum concentrations following the first and fourth injections were 61 ± 17 mcg per mL and 96 ± 31 mcg per mL, respectively.

In 139 children less than or equal to 24 months of age with hemodynamically significant CHD who received Synagis and underwent cardio-pulmonary bypass for open-heart surgery, the mean ± SD serum palmivizumab concentration was 98 ± 52 mcg per mL before bypass and declined to 41 ± 33 mcg per mL after bypass, a reduction of 58% [see Dosage and Administration (2.1)]. The clinical significance of this reduction is unknown.

Specific studies were not conducted to evaluate the effects of demographic parameters on palmivizumab disposition and exposure. However, no effects of gender, age, body weight, or race on palmivizumab serum trough concentrations were observed in a clinical study with 639 children with CHD (less than or equal to 24 months of age) receiving five monthly intramuscular injections of 15 mg per kg of Synagis.

The pharmacokinetics and safety of Synagis liquid solution and Synagis lyophilized formulation administered via intramuscular injection at 15 mg per kg were studied in a cross-over trial of 153 infants less than or equal to 6 months of age with a history of prematurity. The results of this trial indicated that the trough serum concentrations of palmivizumab were comparable between the liquid solution and the lyophilized formulation, which was the formulation used in the clinical studies. A population pharmacokinetic analysis was performed across 22 studies in 1800 patients (1684 pediatric and 116 adult patients) to characterize palmivizumab pharmacokinetics and inter-subject variability in serum concentrations. Palmivizumab pharmacokinetics was described by a two-compartment linear model with an elimination half-life of 24.5 days in pediatric patients. Clearance of palmivizumab in a typical pediatric patient (body weight 4.5 kg) less than or equal to 24 months of age without CHD was estimated to be 11 mL per day with a bioavailability of 70% following intramuscular administration. The inter-patient variability in drug clearance was 48.7% (CV%). Covariate analysis did not identify any factors that could account for the inter-patient variability in order to predict serum concentrations a priori in an individual patient.

12.4 Microbiology

Mechanism of Action

Palmivizumab, a recombinant humanized monoclonal antibody which provides passive immunity against RSV, acts by binding the RSV envelope protein (F RSV) on the surface of the virus and blocking a critical step in the membrane fusion process. Palmivizumab also prevents cell-to-cell fusion of RSV-infected cells.
Neutralization by palivizumab. The safety and efficacy of Synagis were assessed in two randomized, double-blind, placebo-controlled trials of prophylaxis against RSV infection in children at high risk of an RSV-related hospitalization. Trial 1 was conducted during a single RSV season and studied a total of 1502 children less than or equal to 24 months of age with BPD or infants with prematurity birth (less than or equal to 35 weeks gestation) who were less than or equal to 6 months of age at study entry. Trial 2 was conducted over four consecutive seasons among a total of 1287 children less than or equal to 24 months of age with hemodynamically significant congenital heart disease. In both trials participants received 15 mg per kg Synagis or an equivalent volume of placebo intramuscularly once daily for 150 days from randomization. In Trial 1, 99% of all subjects completed the study and 93% completed all five injections. In Trial 2, 96% of all subjects completed the study and 92% completed all five injections. The incidence of RSV hospitalization is shown in Table 1. The results were shown to be statistically significant using Fisher’s exact test.

Table 1: Incidence of RSV Hospitalization by Treatment Group

<table>
<thead>
<tr>
<th>Trial</th>
<th>Placebo</th>
<th>Synagis</th>
<th>Difference Between Groups</th>
<th>Relative Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial 1 Impact-RSV</td>
<td>N</td>
<td>500</td>
<td>1002</td>
<td>50%</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>53 (10.6%)</td>
<td>48 (4.8%)</td>
<td>5.8%</td>
<td></td>
</tr>
<tr>
<td>Trial 2 CHD</td>
<td>N</td>
<td>648</td>
<td>639</td>
<td>4.4%</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>63 (9.7%)</td>
<td>34 (5.3%)</td>
<td>4.5%</td>
<td></td>
</tr>
</tbody>
</table>

In Trial 1, the reduction of RSV hospitalization was observed both in children with BPD (34/266 [12.8%] placebo versus 39/496 [7.9%] Synagis) and in premature infants without BPD (19/234 [8.1%] placebo versus 9/506 [1.8%] Synagis). In Trial 2, reductions were observed in acyanotic (36/305 [11.8%] placebo versus 15/300 [5.0%] Synagis) and cyanotic children (27/343 [7.9%] placebo versus 19/339 [5.6%] Synagis).

The clinical studies do not suggest that RSV infection was less severe among children hospitalized with RSV infection who received Synagis for RSV prophylaxis compared to those who received placebo.

16 HOW SUPPLIED/STORAGE AND HANDLING

Synagis is supplied in single-dose vials as a preservative-free, sterile liquid solution at 100 mg per mL for intramuscular injection. 50 mg vial NDC 60574-4114-1. The 50 mg vial contains 50 mg Synagis in 0.5 mL. 100 mg vial NDC 60574-4113-1. The 100 mg vial contains 100 mg Synagis in 1 mL. The rubber stopper used for sealing vials of Synagis is not made with natural rubber latex.

Storage

Upon receipt and until use, Synagis should be stored between 2°C and 8°C (36°F and 46°F) in its original container, DO NOT freeze. DO NOT use beyond the expiration date.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information). The healthcare provider should discuss the potential benefits and risks of Synagis with the parents or guardians of Synagis recipients. Parents or guardians should be informed of the possible side effects of Synagis and of the signs and symptoms of potential allergic reactions and should be advised of the appropriate actions. Parents or guardians should understand the dosing schedule and the importance of compliance with the full course of therapy.

Synagis® is a registered trademark of MedImmune, LLC.

Manufactured by: MedImmune, LLC Gaithersburg, MD 20878 U.S. License No. 1799 1-877-633-4411

RAL-SYNV17 Component No.: 26920A
Read this Patient Information before your child starts receiving SYNAGIS and before each injection. The information may have changed. This leaflet does not take the place of talking with your child’s healthcare provider about your child’s condition or treatment.

What is SYNAGIS?
SYNAGIS is a prescription medication that is used to help prevent a serious lung disease caused by Respiratory Syncytial Virus (RSV). Your child is prescribed SYNAGIS because he or she is at high risk for severe lung disease from RSV.

SYNAGIS contains man-made, disease-fighting proteins called antibodies. These antibodies help prevent RSV disease. Children at high risk for severe RSV disease often do not have enough of their own antibodies. SYNAGIS is used in certain groups of children to help prevent severe RSV disease by increasing protective RSV antibodies.

SYNAGIS is not used to treat the symptoms of RSV disease once a child already has it. It is only used to prevent RSV disease.

SYNAGIS is not for adults or for children older than 24 months of age at the start of dosing.

Consult your child’s healthcare provider about:
- If you think your child may have RSV.
- If your child has been exposed to someone with RSV.
- When to start and stop SYNAGIS.

Who should not receive SYNAGIS?
Your child 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 itching skin
- swelling of the lips, tongue, or face
- closing of the throat, difficulty swallowing
- difficult, rapid, or irregular breathing
- bluish color of skin, lips, or under fingernails
- muscle weakness or floppiness
- a drop in blood pressure
- unresponsiveness

What should I tell my child’s healthcare provider before my child receives SYNAGIS?
Tell your child’s healthcare provider about:
- any reactions you believe your child has ever had to SYNAGIS.
- any 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.
- any other medical problems.

Tell your child’s healthcare provider about all the medicines your child takes, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your child’s healthcare provider if your child takes a blood thinner medicine.

How is SYNAGIS given?
- SYNAGIS is given as a monthly injection, usually in the thigh (leg) muscle, by your child’s healthcare provider. Your child’s healthcare provider will prescribe the amount of SYNAGIS that is right for your child (based on their weight).
- Your child’s healthcare provider will give you detailed instructions on how to administer SYNAGIS.
  - “RSV season” is a term used to describe the time of year when RSV infections most commonly occur (usually fall through spring in most parts of the country). During this time, when RSV is most active, your child will need to receive SYNAGIS shots. Your child’s healthcare provider can tell you when the RSV season starts in your area.
  - Your child should receive their first SYNAGIS shot before the RSV season starts to help protect them before RSV becomes active. If the season has already started, your child should receive their first SYNAGIS shot as soon as possible to help protect them when exposure to the virus is more likely.

Other possible side effects include skin reactions around the area where the shot was given (like redness, swelling, warmth, or discomfort). These are not all the possible side effects of SYNAGIS. Tell your child’s healthcare provider about any side effect that bothers your child or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to MedImmune at 1-877-633-4411.

General Information about SYNAGIS
Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. This leaflet summarizes important information about SYNAGIS. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about SYNAGIS that is written for health professionals.

For more information, go to www.synagis.com or call 1-877-633-4411.

What are the ingredients in SYNAGIS?
Active Ingredient: palivizumab
Inactive Ingredients: chloride, glycine, and histidine

What is RSV?
Respiratory Syncytial Virus (RSV) is a common virus that is easily spread from person to person. RSV infects nearly all children by their second birthday. In most children, RSV infection is usually no worse than a bad cold. For some children, RSV infection can cause serious lung disease (like pneumonia and bronchiolitis) or breathing problems, and affected children may need to be admitted to the hospital or need emergency care.
Children who are more likely to get severe RSV disease (high-risk children) include babies born prematurely (35 weeks or less) or babies born with certain heart or lung problems.

This Patient Information has been approved by the U.S. Food and Drug Administration.
Synagis® is a registered trademark of MedImmune, LLC.

MedImmune
Manufactured by: MedImmune, LLC
Gaithersburg, MD 20878
Issued March 2014

RAL-SYIV17
Component No.: 26920A