Synagis® (palivizumab) injection, for intramuscular use

INDICATIONS AND USAGE

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.

DOSEAGE 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. (2.1)

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)

DOSEAGE FORMS AND STRENGTHS

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

7 DRUG INTERACTIONS
8 USE IN SPECIFIC POPULATIONS

Uses:

1. Synagis 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.

The following points should be considered when prescribing Synagis:
• 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) [see Clinical Studies (14)].
• The safety and efficacy of Synagis have not been established for treatment of RSV disease.

2 DOSEAGE AND ADMINISTRATION

2.1 Dosing Information

The recommended dose of Synagis is 15 mg per 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. In the northern hemisphere, the RSV season typically commences in November and lasts through April, but it may begin earlier or persist later in certain communities. Synagis serum levels are decreased after cardio-pulmonary bypass [see Clinical Pharmacology (12.3)]. 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. The efficacy of Synagis at doses less than 15 mg per kg, or of dosing less frequently than monthly throughout the RSV season, has not been established.

2.2 Administration Instructions
• DO NOT DILUTE THE PRODUCT.
• DO NOT SHAKE OR VIOLENTLY AGITATE THE VIAL.
• Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use any vials exhibiting particulate matter or discoloration.

Previous significant hypersensitivity reaction to Synagis. (4)

WARNINGS AND PRECAUTIONS

• Anaphylaxis and anaphylactoid shock (including fatal cases), and other severe acute hypersensitivity reactions have been reported. Permanently discontinue Synagis and administer appropriate medications if such reactions occur. (5.1)
• As with any intramuscular injection, Synagis should be given with caution to children with thrombocytopenia or any coagulation disorder. (5.2)
• Palivizumab may interfere with immunological-based RSV diagnostic tests such as some antigen detection-based assays. (5.3, 12.4)

ADVERSE REACTIONS

Adverse reactions occurring greater than or equal to 1% 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.

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Signs and symptoms of anaphylaxis and anaphylactoid shock, including desquamation of skin, widespread urticaria, angioedema, rhinitis, constrictive bronchitis, dyspnea, hypotension, and shock. Anaphylaxis or anaphylactic shock have resulted in death and may be severe and immediately life-threatening. (6.1, 6.2)

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5.2 Coagulation Disorders
Syngas is for intramuscular use only. As with any intramuscular injection, Syngas should be given with caution to children with thrombocytopenia or any coagulation disorder.

5.3 RSV Diagnostic Test Interference
Palivizumab may interfere with immunological-based RSV diagnostic tests such as some antigen detection-based assays. In addition, palivizumab inhibits virus replication in cell culture, and therefore may also interfere with viral culture assays. Palivizumab 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
The most serious adverse reactions occurring with Synagis are anaphylaxis and other acute hypersensitivities reactions [see Warnings and Precautions (5.1)].

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 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 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.

Immunogenicity
In Trial 1, the incidence of anti-palivizumab antibody following the fourth injection was 1.1% in the placebo group and 0.7% in the Synagis group. In children receiving Synagis for a second season, one of the fifty-six children had transient, low titer reactivity. This reactivity was not associated with adverse events or alteration in serum concentrations. Immunogenicity was not assessed in Trial 2.

A trial of high-risk preterm children less than or equal to 24 months of age was conducted to evaluate the immunogenicity of the lyophilized formulation of Synagis (used in Trials 1 and 2 above) and the liquid formulation of Synagis. Three hundred seventy-nine children contributed to the 4 to 6 months post-final dose analysis. The rate of anti-palivizumab antibodies at this time point was low in both formulation groups (anti-palivizumab antibodies were not detected in any subject in the liquid formulation group and were detected in one subject in the lyophilized group (0.5%), with an overall rate of 0.3% for both treatment groups combined).

These data reflect the percentage of children whose test results were considered positive for antibodies to palivizumab in an enzyme-linked immunosorbent assay (ELISA) and are highly dependent on the sensitivity and specificity of the assay.

The ELISA has substantial limitations in detecting anti-palivizumab antibodies in the presence of palivizumab. Immunogenicity samples tested with the ELISA assay likely contained palivizumab at levels that may interfere with the detection of anti-palivizumab antibodies.

An electrochemical luminescence (ECL) based immunogenicity assay, with a higher tolerance for palivizumab presence compared to the ELISA, was used to evaluate the presence of anti-palivizumab antibodies in subject samples from two additional clinical trials. The rates of anti-palivizumab antibody positive results in these trials were 1.1% and 1.5%.

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
Pregnancy Category C: Synagis is not indicated for adult usage. It is not known whether Synagis 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
Palivizumab is a humanized monoclonal antibody (IgG1k) produced by recombinant DNA technology, directed to an epitope in the A antigenic site of the F protein of RSV. Palivizumab 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 V<sub>κ</sub> genes C<sub>κ</sub> and C<sub>ε</sub>. The human light chain sequence was derived from the constant domain of C<sub>κ</sub> and the variable framework regions of the V<sub>κ</sub> gene K104 with j<sub>κ</sub>-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. Palivizumab 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 palivizumab 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 palivizumab 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
Palivizumab 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 with congenital heart disease (CHD), the mean half-life of palivizumab was 20 days and monthly intramuscular doses of 15 mg per kg achieved >60% daily trough serum drug 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 86 ± 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 palivizumab 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 palivizumab pharmacokinetics. However, no effects of gender, age, body weight, or race on palivizumab 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 palivizumab 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 palivizumab pharmacokinetics and inter-subject variability in serum concentrations. Palivizumab pharmacokinetics was described by a two-compartment linear model with an elimination half-life of 24.5 days in pediatric patients. Clearance of palivizumab in a population of pediatric patients (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
Palivizumab, a recombinant humanized monoclonal antibody which provides passive immunity against RSV, acts by binding the RSV envelope fusion protein (F protein) on the surface of the virus and blocking a critical step in the membrane fusion process. Palivizumab also prevents cell-to-cell fusion of RSV-infected cells.
Interference of RSV Diagnostic Assays by Palivizumab

Palivizumab binds a highly conserved region on the extracellular domain of mature RSV F, referred to as antigenic site II or site A, which encompasses amino acids 262 to 275. All RSV mutants that exhibit resistance to palivizumab have been shown to contain amino acid changes in this region on the F protein.

F protein sequence variations within antigenic site A: Amino acid substitutions in antigenic site A selected either in cell culture, in animal models, or in human subjects that resulted in palivizumab resistance were N262D, N268I, K272E/Q, and S275F/L. RSV variants expressing the K272E substitution in F protein showed a 1.64 ± 1.73-fold decrease in susceptibility (i.e., fold increase in EC50 value) when compared to the wild-type RSV, while variants containing the N262D, S275F/L, or K272E/Q substitutions showed a greater than 25,000-fold decrease in susceptibility to palivizumab. The N268I substitution conferred partial resistance to palivizumab; however, fold changes in susceptibility were not quantified for this mutant. Studies carried out to investigate the mechanism of virus escape from palivizumab showed a correlation between antibody binding and virus neutralization. RSV with substitutions in antigenic site A that were resistant to neutralization by palivizumab did not bind to palivizumab.

At least one of the palivizumab resistance-associated substitutions, N262D, K272E/O, or S275F/L was identified in 8 of 128 clinical RSV (59% RSV A and 67% RSV B) isolates from subjects who failed immunoprophylaxis, resulting in a combined resistance-associated mutation frequency of 6.3%. A review of clinical findings revealed no association between antigenic A site sequence changes and RSV disease severity among children receiving palivizumab immunoprophylaxis who develop RSV lower respiratory tract disease.

Analysis of 254 clinical RSV isolates (145 RSV A and 109 RSV B) collected from immunoprophylaxis-naive subjects revealed palivizumab resistance-associated substitutions in 2 (1 with N262D and 1 with S275F), resulting in a resistance-associated-associated mutation frequency of 0.79%.

F protein sequence variations outside antigenic site A: In addition to the sequence variations in antigenic site A variations to confer palivizumab resistance, F protein substitutions T100A, G133S, G165D/V406I, T326A, V450A in RSV A, and T741, I147V, I206L, S285G, V450I, T455S in RSV B were identified in viruses isolated from failures of immunoprophylaxis. These substitutions were not identified in RSV F sequences derived from 254 clinical isolates from immunoprophylaxis-naive subjects and thus are considered treatment-associated and non-polymorphic. Recombinant RSV B encoding the T100A substitution in F protein exhibited palivizumab sensitivity (EC50 value = 0.39 ± 0.02 mcg per mL) similar to recombinant wild-type RSV B (EC50 value = 0.17 ± 0.02 mcg per mL).

Palivizumab susceptibility of RSV encoding common F protein sequence polymorphisms located proximal to antigenic site A was evaluated. Recombinant RSV A encoding N276S (EC50 value = 0.72 ± 0.07 mcg per mL) and recombinant RSV B with S276N (EC50 value = 0.42 ± 0.04 mcg per mL), exhibited sensitivities comparable to the corresponding recombinant wild-type RSV A (EC50 value = 0.63 ± 0.22 mcg per mL) and RSV B (EC50 value = 0.23 ± 0.07 mcg per mL). Likewise, RSV B clinical isolates containing the polymorphic variation V278A were at least as sensitive to neutralization by palivizumab (EC50 range 0.08-0.45 mcg per mL) as laboratory strains of wild-type RSV B (EC50 value = 0.54 ± 0.08 mcg per mL). No known polymorphic or non-polymorphic sequence variations outside the antigenic site A or on RSV F have been demonstrated to render RSV resistant to neutralization by palivizumab.

Interference of RSV Diagnostic Assays by Palivizumab

Interference with immunologically-based RSV diagnostic assays by palivizumab has been observed in laboratory studies. Rapid chromatographic/enzyme immunoassays (CIA/EIA), immunofluorescence assays (IFA), and direct immunofluorescence assays (DFA) using monoclonal antibodies targeting RSV F protein may be inhibited. Therefore, caution should be used in interpreting negative immunological assay results when clinical observations are consistent with RSV infection. A reverse transcriptase-polymerase chain reaction (RT-PCR) assay, which is not inhibited by palivizumab, may prove useful for laboratory confirmation of RSV infection [see Warnings and Precautions (5.3)].
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.

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 when SYNAGIS will be given.
  - “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.

SYNAGIS is needed every 28-30 days during the RSV season. Each dose of SYNAGIS helps protect your child from severe RSV disease for about a month. Keep all appointments with your child’s healthcare provider.

- If your child misses an injection, talk to your healthcare provider and schedule another injection as soon as possible.
- Your child may still get severe RSV disease after receiving SYNAGIS; talk to your child’s healthcare provider about what symptoms to look for. If your child has an RSV infection, they should continue to get their scheduled SYNAGIS injections to help prevent severe disease from new RSV infections.
- If your child has certain types of heart disease and has corrective surgery, your healthcare provider may need to give your child an additional SYNAGIS injection soon after surgery.

What are the possible side effects of SYNAGIS?

Synagis may cause serious side effects including:

- Severe allergic reactions (may occur after any dose of SYNAGIS). Such reactions may be life-threatening or cause death.

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.

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