Hailey's Hope Foundation's
Fourth Annual

Beach Bash

Cocktail & Dinner Reception

Manursing Island Club

Saturday, June 2, 2012

We proudly honor

Olivia and Lawrence Blau

recipients of the

Hailey Zion Memorial Award

for Community Spirit,

in recognition of

their work with the

Hailey's Hope Foundation.

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Hailey's Hope Foundation's Fourth Annual

Beach Bash

Cocktail & Dinner Reception

to benefit families with premature and critically ill babies in Neonatal Intensive Care Units (NICUs) at Maria Fareri Children's Hospital and other New York area hospitals

Presenting

The Hailey Zion Memorial Award For Community Spirit

to

Olivia and Lawrence Blau

Saturday, June 2, 2012
Manursing Island Club
Rye, New York

Premier Sponsors
Reckson, A Division of SL Green
Lincoln Land Services, LLC

Evening Events

FOOD & DRINK

Premium Open Bar
Passed Hors D'oeuvres
Dinner

REMARKS

Donna Zion
Vice President of Hailey's Hope Foundation
Hailey's mom

"HAILEY'S HOPE FOUNDATION" VIDEO

GUEST SPEAKER

The McElroy Family
A Hailey's Hope Foundation NICU family

PRESENTATION OF THE HAILEY ZION MEMORIAL AWARD FOR COMMUNITY SPIRIT

to

Olivia and Lawrence Blau

AUCTION & RAFFLES

DESSERT & COFFEE

Good Evening!

It is our pleasure and privilege to have you here tonight for Hailey's Hope Foundation's Fourth Annual *Beach Bash* Benefit. As we enjoy this evening, we have the joy of knowing that our efforts have brought hope, comfort and essential support to over 800 NICU families in need as they face and cope with the challenges of caring for their babies in the Neonatal Intensive Care Unit (NICU).

Tonight, we are pleased to pay tribute to longtime Westchester residents and philanthropists, Olivia and Lawrence Blau. Their tremendous commitment and dedication to serving the needs of others, especially in the NICU community, have impacted the lives of many families locally, nationally and internationally. It is our distinct honor to present Olivia and Lawrence Blau with the 2012 Hailey Zion Memorial Award for Community Spirit to salute their accomplishments.

As more and more families are faced with the reality of having babies born prematurely and critically ill, the demand for Hailey's Hope Foundation's unique and essential support continues to grow. In May 2012, we partnered with the new Orange Regional Medical Center in Middletown, New York and we are thrilled to reach even more NICU families in the Orange County region. We have made tremendous progress, yet there is still much more to be done. Your support this evening will bring us steps closer to our goals to bring greater financial assistance, emotional support, and educational information to NICU families to help them through this difficult time and be there for their babies when needed the most.

It is truly inspiring to see the generosity of family, friends and supporters who have helped us raise close to $400,000 since we formed in December 2007. We will continue to work hard to be a valuable support system for NICU families during this critical time.

Thank you for your generosity this evening. We are deeply grateful to you and look forward to your continued support.

Yours truly,

Jeffrey Randazzo
President

The Hailey Zion Memorial Award For Community Spirit

The Hailey Zion Memorial Award for Community Spirit is awarded to an individual whose life and work exemplifies a strong commitment to their community and a heartfelt desire to share their time, talent, and heart to help others in need. It is these qualities that reflect the spirit of Hailey's Hope Foundation and represent our wish to offer light to those in a time of darkness.

This award is dedicated to the memory of our little angel Hailey Zion, a beautiful baby girl who was born too soon.

The 2012 Hailey Zion Memorial Award for Community Spirit is presented to:

Olivia and Lawrence Blau

in recognition of their extraordinary dedication to serving the needs of NICU families.

Past Award Recipients:

2011 Edmund F. La Gamma, MD
Director of The Regional Neonatal Center at Maria Fareri Children's Hospital

Edward A. Diana
Orange County Executive

2010 Brenda and John Fareri
Co-Founders of Maria Fareri Children's Hospital

Olivia and Lawrence Blau

2012 Hailey Zion Memorial Award for Community Spirit Recipients

Hailey's Hope Foundation welcomes this opportunity to recognize Olivia and Lawrence Blau for their tremendous commitment and contributions to helping others in need, especially in the NICU community. For many years, Olivia and Lawrence Blau have passionately shared their time and talents with organizations working to improve the lives of many underserved families and children, locally, nationally and internationally.

Olivia Blau is a self-employed Doctor of Dental Surgery and maintains a private Family and General Dentistry practice in Briarcliff Manor, New York. In addition, she holds executive positions in nonprofit organizations, including President of Maggie's Fund Foundation, and Vice President of Horncrest Foundation Inc. Volunteering is an important part of Olivia's life. She has devoted her time and expertise to bringing dental care to various clinics in New Mexico and Jamaica. At the Community Pantry of Gallup, New Mexico, Olivia has also helped to expand their Food For Kids program, which provides nourishing weekend meals to 475 of the most needy school children in the region over a 36-week period.

Lawrence Blau is a self-employed accountant and certified financial planner. He serves as the President of Horncrest Foundation Inc. and the Vice President of Maggie's Fund Foundation. For the past 11 years, Lawrence has actively participated in many charitable causes, including Big Brother of Westchester, the Ossining Food Pantry and the Community Pantry of Gallup in New Mexico. With a focus on education, Lawrence has dedicated considerable time and expertise to helping improve the quality of education for underprivileged schoolchildren in Cambodia, New Mexico, on the Navajo Reservation, and in Harlem, New York. Together, Lawrence and Olivia have been instrumental in distributing numerous special educational computers (called the XOs) to various schools in these areas.

Olivia and Lawrence joined forces with Hailey's Hope Foundation a few years ago. With their personal knowledge of the NICU and the economic hardships families face with lengthy NICU hospitalizations, they committed to help. Olivia and Lawrence have significantly broadened the reach of Hailey's Hope Foundation's Financial Support Program, which assists families in need with lodging, meals, transportation, baby supplies and other essential, non-medical expenses. Their passion, drive and contributions have brought hope and comfort to many more struggling NICU families, enabling them to keep focus on what matters the most – their baby's survival and development.

It is with deepest appreciation and admiration that Hailey's Hope Foundation presents its 2012 Hailey Zion Memorial Award for Community Spirit to Olivia and Lawrence Blau. We are grateful to Olivia and Lawrence for all of their efforts in helping Hailey's Hope Foundation meet the needs of NICU families, and for everything they do for other underserved families and children.

Residing in Ossining, New York, Olivia and Lawrence are the proud parents of four children: Dr. Jonathan Blau, Lindsay La Fleur, and twins Evan and Russell Blau.

Beach Bash Committee

Chairperson

Donna Zion

Committee

Debra Randazzo, Doreen Zion, Ann Siegel, Dawn Singer,
Marvin Siegel, Suzanne Decina

"No one can do everything, but everyone can do something"
— Author Unknown

Dear Friends:

Thank you for joining us on this special evening to celebrate the great accomplishments of Hailey's Hope Foundation in helping NICU families and to pay tribute to Olivia and Lawrence Blau, extraordinary individuals who have profoundly touched and improved the lives of many families in our communities.

The outpouring of support for this year's event is incredibly moving and inspiring. I want to express our sincere appreciation for the support of our premier sponsors: Reckson, A Division of SL Green and Lincoln Land Services, LLC., our participating sponsors: Mr. and Mrs. Matt DiLiberto and The Holliday Foundation and this evening's dessert sponsors, the Galiano Family. We are grateful to all of our very generous donors for making tonight a great success, including businesses and families who donated wonderful items to our Auction and Raffle, purchased tickets, and purchased advertisements in our Reception Journal.

This evening would not be as memorable an event without the hard work, creativity and commitment of our Beach Bash Committee. Thank you for everything. I would also like to thank Lisa Guinta for the beautiful design of our Reception Journal and Manursing Island Club for the beautiful setting and wonderful food and service.

On behalf of Hailey's Hope Foundation and the Committee, thank you for your continued support.

Enjoy!

Warm regards,
Donna Zion
Chairperson

Hailey's Hope Foundation

wishes to thank the following donors for their generous support

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The DiLiberto Family
The Holliday Foundation

DESSERT SPONSOR

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Special thanks to our Auction & Raffle donors

Sharp Electronics Corporation
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Cate Porter Williams
Mr. & Mrs. Steve Wechsler

The Zion Families
Chelsea Piers Sports & Entertainment Complex (NYC)
The Broadway Comedy Club
Mr. and Mrs. Ray Muntz
The Koltis Family

List as of 5/15

Our NICU Graduates

MATTHEW RANDAZZO

Born: 28 weeks at 2 lbs. 8 oz.

NICU stay: 62 days

ALENCE ZION

Born: 30 weeks at 2 lbs. 15 oz.

NICU stay: 42 days

JEFFREY RANDAZZO

Born: 38 weeks at 7 lbs. 14 oz.

NICU stay: 1 day

JAKE ZION

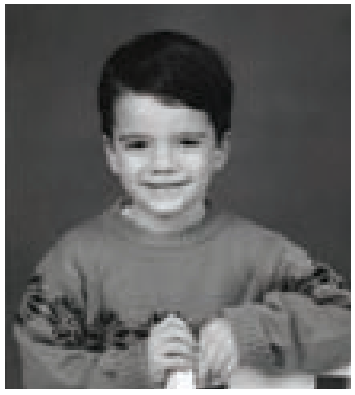
Born: 32 weeks at 3 lbs. 8 oz.

NICU stay: 28 days

DYLAN RANDAZZO

Born: 33 weeks at 4 lbs. 5 oz.

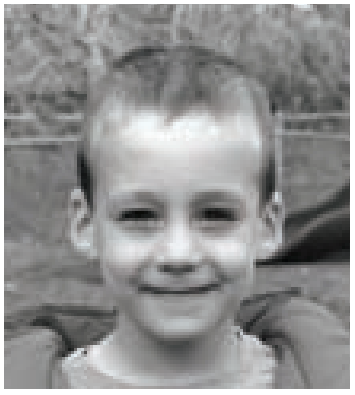
NICU stay: 21 days



KADEN ZION

Born: 34 weeks at 4 lbs. 6 oz.

NICU stay: 10 days



TAYLOR DECINA

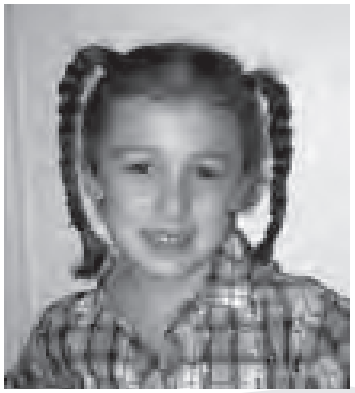
Born: 40 weeks at 8 lbs. 1 oz.

NICU stay: 4 days

MADISON DECINA

Born: 36 weeks at 5 lbs. 15 oz.

NICU stay: 14 days



Hailey's Hope Foundation is a 501(c)(3) nonprofit organization dedicated to supporting families with premature and critically ill babies in New York area Neonatal Intensive Care Units (NICUs). During this crucial time, families play a vital role in the NICU team and their baby's survival, health and development. Hailey's Hope Foundation addresses urgent needs for financial assistance, emotional support, and educational information, so families can better cope with their baby's hospitalization. We also raise money to fund neonatal clinical research and purchase advanced medical equipment to give more babies a fighting chance.

As a grassroots, volunteer-based organization, we carry out our mission through targeted programs and initiatives:

Financial Assistance: A NICU stay can last weeks or months, and the additional expenses can quickly become a serious hardship, especially for economically strained families. We help families in need with non-medical expenses, including lodging, transportation, and meals, so they can spend as much time as possible at the hospital with their baby and NICU team.

Education & Resources: Families can use our website (www.haileyshopefoundation.org) to access educational information, neonatal research and other resources, including a growing community of NICU parents who share their experience. Our longer-term goals include developing in-hospital NICU family resource centers and parent support groups.

Additional Support: Leaving the highly specialized, 24-hour care of NICU doctors and nurses is daunting for any parent. At discharge, we supply families with care packages to help ease the anxiety of transitioning home with their tiny miracles. Our packages contain baby care items, supplies and important information about post-NICU issues, such as finding local resources for early intervention and special needs.

Hailey's Hope Foundation was created in December 2007 by four couples that endured many NICU crises together and saw first hand the startling void in support for families during this incredibly difficult time. We realized how overwhelming and frightening a NICU hospitalization quickly became, how unprepared families were to handle this crisis and the toll it took on them, and how few avenues there were for families to turn to for help. Hailey's Hope Foundation is changing this reality. We are working hard to be a valuable resource for NICU families, to give a voice to their needs, and to make their NICU paths a little easier to walk.

Currently, we are partnered with the Regional NICU at Maria Fareri Children's Hospital at Westchester Medical Center in Valhalla, New York and the new Orange Regional Medical Center in Middletown, New York. To date, we have raised close to $400,000, provided support to over 800 NICU families, and purchased essential medical equipment and supplies for the NICU.

Hailey's Hope Foundation was created in loving memory of our little angel, Hailey, the daughter of Isaac and Donna Zion who was born prematurely and passed away shortly after birth in 2003.

Thank you ...

Dear Hailey's Hope Foundation:

"I wanted to thank you from the bottom of my heart for your generous support. My daughter, Kelley, was quite emotional regarding the generous gift of support you gave to her family while one of her twins was in the NICU. I can't even begin to tell you how this helps them out. Since August 2011, the months of travel from Orange County to the NICU at Mt. Sinai Hospital in Manhattan with gas, tolls, parking, meals, etc. really added up. Avery went home and her twin brother, Ethan, was transferred to Blythdale Children's Hospital in Westchester. Although the trip to Blythedale has lessened the financial burden somewhat, they are still faced with daily expenses of gas and tolls. I will never stop singing your foundation's praises. It is comforting to know that there are individuals that understand fully the stresses and burdens, both emotionally and financially, placed on a family with children in this situation. Again, thank you so very, very much!"

Dianne R. Morgan, Highland Mills, NY

"My family and I would like to thank you for your assistance while our girls were in the NICU at Maria Fareri Children's Hospital. Our twin girls were born at 32 weeks due to a high-risk pregnancy. Your support, understanding and caring during such a stressful time was GREATLY appreciated. Thank you for being there for my family and others."

The De Luccia Family,
Pound Ridge, NY

"Thank you so much for your financial support while baby Erica has been in the NICU in Manhattan. Erica was born very sick and has been in the NICU now for 5 months. This has been difficult on everyone, including my 4-year-old son, Declan. Without your support, we would not be able to be there for Erica as much as we have been. We are so grateful for everything you have done for our family."

The Burns Family,
Campbell Hall, NY

"We greatly appreciate the support you gave us at Maria Fareri Children's Hospital back in April. It was a ray of sunshine and hope during a very difficult time when our twin boys were in the NICU. We are blessed to have them both home with us now. We are very grateful for your help."

The Rosenberg Family,
Cortlandt Manor, NY

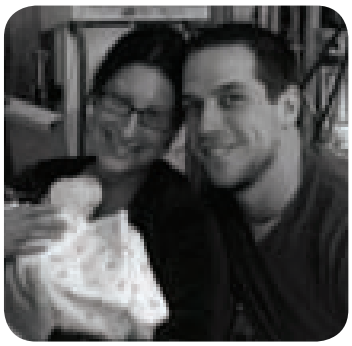
"Two years ago I spent many days in the NICU because my son and his wife had a preemie (1lb. 10 oz.). I came to hold the baby and be a support. While there, I became familiar with your organization and the incredible support you give to the parents who are struggling emotionally and financially. I was so impressed."

Ms. Plath, Hartsdale, NY

"I wanted to write you a sincere note of thanks for your generous support for my husband and I as we stayed at the Ronald McDonald House to be closer to our baby. We feel so grateful to have received your support for lodging, transportation back and forth to the hospital and help with parking. It was a great help."

The Evangelista Family, West Point, NY

The McElroy Family…Their NICU Story



The evening of January 14th was like one typical of any pregnancy. There were "normal" feelings of pregnancy at 24 weeks, but nothing that seemed out of the ordinary, especially after reading all the pregnancy books. At about 3:45 am on January 15, our "normal" pregnancy ended and quickly turned painful. The pains that were so commonly associated with pregnancy turned out to be labor pains. That morning, my water broke and I gave birth to our beautiful baby daughter, Kenley Rian—16 weeks early! Not only was Kenley's arrival a complete shock to us, but she made her grand entrance into this world at our home. At 4:04 a.m., my husband, Graig, now OB and first responder, delivered Kenley. He performed rescue breathing on her until the EMTs arrived. The EMTs and first responders were amazing and quickly got Kenley to Arden Hill Hospital. Due to Kenley's extreme prematurity, she was immediately transferred to the Regional NICU at Maria Fareri Children's Hospital at Westchester Medical Center in Valhalla, about 40 miles away. This NICU was her home for the next 122 days.

Everything seemed so normal and then changed in an instant. We were thrown into a situation that we never imagined possible. It was frightening! We had absolutely no idea what we were in for or what was going to happen. Life in the NICU took its toll on us. Kenley's premature birth at 24 weeks and the surgeries and procedures that followed were hard to overcome. On her second day of life, she developed a significant cerebral bleed, which led to an ommaya reservoir being put in, and then a shunt. During her first 5 precious months of life, she underwent three brain surgeries (ommaya, shunt and shunt revision) and one heart surgery (to close her pda). We were constantly reminded how critical and beneficial it was for us to be there for Kenley, for her survival and development. In our baby girl's fight for her life, we knew she needed us and our love and support more than anything. It was difficult to juggle schedules and hospital visits. We made sure that we were there for her each and every day, for 122 days, snow, rain or shine. Graig would visit Kenley in the morning before work and I would go in the evening after work. Living in Chester, New York, we traveled approximately 40 miles each way to the hospital. Some days when we got home and called the NICU for updates on Kenley's condition, we would head right back to the hospital if we got bad news. We were back and forth a lot and easily added 20,000 miles on our brand new car, but we wouldn't have changed a single trip.

Today, Kenley is doing amazing! She is exactly where she should be, according to her corrected age. We still have a long road ahead of us, and there are definite possibilities for obstacles, but right now, she is a very happy baby who is doing well. We truly believe that our presence during her time in the hospital, along with the great staff at the RNICU, played a significant part in where she is today.

Hailey's Hope Foundation had an important role in helping us be there for Kenley. The support they gave us during our time in the hospital helped to ease our fears and made all of our trips easier. We are so grateful for what they did for us, and what they continue to do for families with babies in the NICU. When you find yourself in a critical situation like we did, having supporters like Hailey's Hope there makes a tremendous difference.

Everything Panned Out

Rye Girls Scouts and HHF feed Ronald McDonald House families

Families staying at the Ronald McDonald House of the Greater Hudson Valley (on the grounds of Maria Fareri Children's Hospital) awoke to a special treat on Saturday, March 24, 2012. The Girl Scouts Heart of the Hudson Rye Troop 2820, together with HHF volunteers, spent the morning at the House preparing a delicious brunch for all of the families. From flipping pancakes, cooking turkey bacon, washing and cutting fruit, preparing bagel platters, and baking brownies, the volunteers covered every detail. The Girl Scouts also made beautiful tissue paper flowers to share with the children undergoing treatment at the hospital.

Viva Italia!

Harness Racing Museum, Goshen

The Hailey's Hope Foundation Viva Italia Dinner Auction Fundraiser on October 15, 2011 drew a great crowd at Harness Racing Museum in Goshen, New York. Sponsored by Delancey's Bar and Restaurant, it was a fun and successful evening. Orange County Executive, Edward A. Diana, was presented with the Hailey Zion Memorial Award for Community Spirit for his dedication to serving the needs of the community. Proceeds benefitted NICU families at Maria Fareri Children's Hospital, the new Orange Regional Medical Center, and other New York area hospitals.

and Activities

Fiesta en la Playa

Manursing Island Club, Rye

On April 30, 2011, Hailey's Hope Foundation hosted its Third Annual Fiesta en la Playa Cocktail and Dinner Reception at Manursing Island Club in Rye. The event was a great success and raised over $85,000 for its programs that support the needs of many local families struggling to cope with their baby's hospitalization in the Neonatal Intensive Care Unit (NICU). Hailey's Hope Foundation was proud to present Dr. Edmund F. La Gamma, Chief of Newborn Medicine and Director of the Regional NICU at Maria Fareri Children's Hospital, with the Hailey Zion Memorial Award for Community Spirit in recognition of his extraordinary commitment to improving the lives of NICU babies. The event was sponsored by: our Premier Sponsors - Reckson, A Division of SL Green and New York Capital Markets Group of Jones, Lang LaSalle; our Participating Sponsors – Securitas Security Services, USA, Inc. and CB Richard Ellis, Inc.; our Invitation Sponsor – Saugatuck Construction Group, LLC; and our Dessert Sponsor – Palotta Landscaping Inc.

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Maria Fareri Children's Hospital
Westchester Medical Center-NY Medical College
Valhalla, N.Y. 10595
(914) 493-8558

maria fareri children's hospital

Congratulations and Best Wishes to
Hailey's Hope Foundation
for their Outstanding Achievements in Health Care and Philanthropy

Edmund F. La Gamma, M.D. & Faculty

Gad Alpan, M.D.
Johanna Calo, M.D.
Semsa Gogcu, M.D.
Joseph Hall, M.D.
Martin Katzenstein, M.D.
Yogangi Malhotra, M.D.
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Lincoln Land Services LLC proudly supports

HAILEY'S HOPE FOUNDATION

in their continued efforts to assist, support and comfort NICU families.

We wish you continued success.

Chris Hein - Drew Melchionni - Vincent Ponte

LINCOLN LAND SERVICES

TRANSACTION MANAGEMENT EXPERTS

The hurdles preemies must overcome *don't end in the NICU**

Respiratory syncytial virus (RSV) is a serious concern that premature babies may face

RSV is easily spread—infecting almost all children by their second birthday

- It is spread by sneezing, coughing, or physical contact (such as kissing, touching, or hugging)

RSV disease is the #1 cause of hospitalizations in babies under one year of age in the US

- In most healthy babies, RSV infection usually causes mild to moderate cold symptoms, but in certain high-risk babies it can cause hospitalization
- RSV can cause severe lung infection and lead to complications such as bronchiolitis and pneumonia in certain high-risk babies:
  —Preemies —Babies who develop chronic lung disease —Babies born with heart disease

MedImmune, the maker of Synagis®, is committed to helping protect vulnerable high-risk babies against severe RSV disease

- Synagis is an FDA-approved medication that may help protect high-risk babies against severe RSV disease during the RSV season

For more information about severe RSV disease and Synagis, visit www.synagis.com.

*NICU = neonatal intensive care unit.

SYNAGIS®
PALIVIZUMAB

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Important Safety Information

What is Synagis® (palivizumab)?

Synagis 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.

Who should not receive Synagis?

Children should not receive Synagis if they have ever had a severe allergic reaction to it. Signs and symptoms of a severe allergic reaction could include itchy rash; swelling of the face; difficulty swallowing; difficulty breathing; bluish color of the skin; muscle weakness or floppiness; 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.

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

What are the side effects with 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.

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 full product information, including patient information, on the following pages.

MedImmune
Gaithersburg, MD 20878 Customer Support Network: 1-877-633-4411 10834 ZN Printed in USA May 2012

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SYNAGIS safely and effectively. See full prescribing information for SYNAGIS.

Synagis® (palivizumab) injection for intramuscular use
Initial U.S. Approval: 1998

RECENT MAJOR CHANGES

Warnings and Precautions
RSV Diagnostic Test Interference (5.3) 4/2012

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. (1)

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. (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)

DOSAGE FORMS AND STRENGTHS

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

CONTRAINDICATIONS

Previous significant hypersensitivity reaction to Synagis. (4)

WARNINGS AND PRECAUTIONS

- Anaphylaxis and anaphylactic 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 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. (8.4)

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

Revised: 4/2012

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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. 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 following point should be considered when prescribing Synagis:

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

2 DOSAGE 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 VIGOROUSLY 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.
- 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.
- 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.
- 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.

3 DOSAGE FORMS AND STRENGTHS

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

4 CONTRAINDICATIONS

Synagis is contraindicated in children who have had a previous significant hypersensitivity reaction to Synagis [see *Warnings and Precautions* (5.1)].

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

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. Signs and symptoms may include urticaria, pruritus, angioedema, dyspnea, respiratory failure, cyanosis, hypotonia, hypotension, and unresponsiveness. 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 anaphylaxis or other significant hypersensitivity reaction occurs, administer appropriate medications (e.g., epinephrine) and provide supportive care as required.** If a mild hypersensitivity reaction occurs, clinical judgment should be used regarding cautious readministration of Synagis.

5.2 Coagulation Disorders

Synagis is for intramuscular use only. As with any intramuscular injection, Synagis 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 hypersensitivity 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=1142) 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 70 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 ($IgG1\kappa$) 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_H genes Cor and Cess. The human light chain sequence was derived from the constant domain of C_κ and the variable framework regions of the V_L gene κ104 with J_κ-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 without congenital heart disease (CHD), the mean half-life of palivizumab was 20 days and monthly intramuscular doses of 15 mg per kg achieved mean ± SD 30 day 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 serum 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 systemic exposure. 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.

12.4 Microbiology

Mechanism of Action

Palivizumab acts by binding the RSV envelope fusion protein (RSV *F*) 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.

Antiviral Activity

The antiviral activity of palivizumab was assessed in a microneutralization assay in which increasing concentrations of antibody were incubated with RSV prior to addition of the human epithelial cells HEp-2. After incubation for 4-5 days, RSV antigen was measured in an ELISA assay. The neutralization titer (50% effective concentration [EC_{50}]) is expressed as the antibody concentration required to reduce detection of RSV antigen by 50% compared with untreated virus-infected cells. Palivizumab exhibited median EC_{50} values of 0.65 mcg per mL (mean 0.75 ± 0.53 mcg per mL; n=69, range 0.07-2.89 mcg per mL) and 0.28 mcg per mL (mean 0.35 ± 0.23 mcg per mL; n=35, range 0.03-0.88 mcg per mL) against clinical RSV A and RSV B isolates, respectively. The majority of clinical RSV isolates tested (n=97) were

collected from subjects across the United States (CA, CO, CT, IL, MA, NC, NY, PA, RI, TN, TX, VA), with the remainder from Japan (n=1), Australia (n=4) and Israel (n=2). These isolates encoded the most common RSV F sequence polymorphisms found among clinical isolates worldwide.

Palivizumab serum concentrations of greater than or equal to 40 mcg per mL have been shown to reduce pulmonary RSV replication in the cotton rat model of RSV infection by 100-fold.

Resistance

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/M/N/Q/T, and S275F/L. RSV variants expressing the K272N substitution in F protein showed a 5184 ± 1731-fold decrease in susceptibility (i.e., fold increase in EC_{50} value) when compared to the wild-type RSV, while variants containing the N262D, S275F/L, or K272E/M/Q/T 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/Q, or S275F/L was identified in 8 of 126 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 mutation frequency of 0.79%.

F protein sequence variations outside antigenic site A: In addition to the sequence variations in antigenic site A known to confer palivizumab resistance, F protein substitutions T105A, G139S, N165D/Y406H, T326A, V450A in RSV A, and T74I, A147V, I206L, S398G, V450I, T455I 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 S398G substitution exhibited palivizumab sensitivity (EC_{50} value = 0.39 ± 0.02 mcg per mL) similar to recombinant wild-type RSV B (EC_{50} 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 (EC_{50} value = 0.72 ± 0.07 mcg per mL), and recombinant RSV B with S276N (EC_{50} value = 0.42 ± 0.04 mcg per mL), exhibited sensitivities comparable to the corresponding recombinant wild-type RSV A (EC_{50} value = 0.63 ± 0.22 mcg per mL) and RSV B (EC_{50} 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 (EC_{50} range 0.09-0.45 mcg per mL) as laboratory strains of wild-type RSV B (EC_{50} value = 0.54 ± 0.08 mcg per mL). No known polymorphic or non-polymorphic sequence variations outside the antigenic site A 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)].

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis, mutagenesis, and reproductive toxicity studies have not been performed.

14 CLINICAL STUDIES

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 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 both trials participants received 15 mg per kg Synagis or an equivalent volume of placebo via intramuscular injection monthly for five injections and were followed 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

Trial		Placebo	Synagis	Difference Between Groups	Relative Reduction
Trial 1 Impact-RSV	N	500	1002		
	Hospitalization	53 (10.6%)	48 (4.8%)	5.8%	55%
Trial 2 CHD	N	648	639		
	Hospitalization	63 (9.7%)	34 (5.3%)	4.4%	45%

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.

There is no latex in the rubber stopper used for sealing vials of Synagis.

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

- **"See 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.

MedImmune

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

RAL-SYNW15
Component No.: 10832

Information for Patients and Their Caregivers

SYNAGIS® (sĭ-nă-jĭs)

(palivizumab)

Injection

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.
  - See "Who should not take SYNAGIS?" for a list of signs and symptoms.
- Unusual bruising or groups of tiny red spots on the skin.

Call your child's healthcare provider or get medical help right away if your child has any of the serious side effects listed above after any dose of SYNAGIS.

Common side effects of SYNAGIS include:

- fever
- rash

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

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RAL-SYNV15
Component No.: 10973

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Our Best Wishes and
Congratulations to
Hailey's Hope Foundation for
their outstanding work in helping
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NYSPA

New York State Perinatal Association

The New York Perinatal Association would like to recognize:

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For their commitment to families with premature babies.

www.nysperinatal.org

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We could not do this without you.

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To our special angel, Hailey:

Even though you are not here to play with us, we know you are in heaven playing with the angels and smiling down on us.

We love you and miss you everyday.

Thank you for keeping us safe.

Love,

Alence, Jake, Kaden, Matthew, Jeffrey, Dylan,
Taylor, JD, Maddie, Amber, Kaitlyn & Leah

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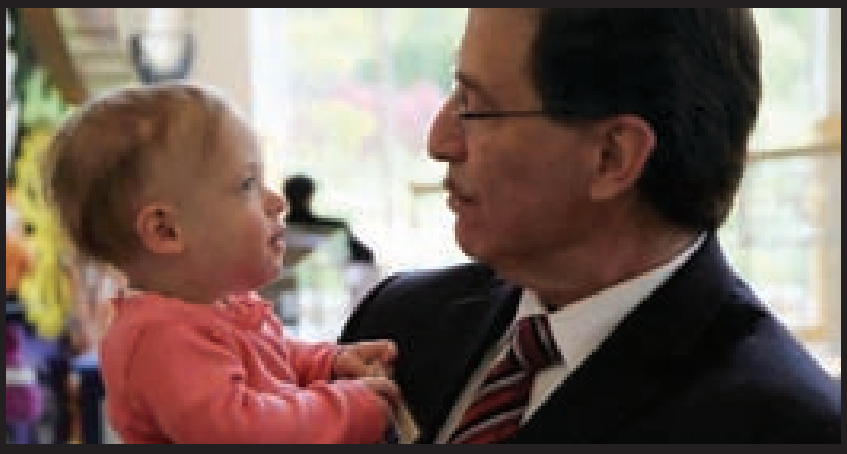
MARKETING COMMUNICATIONS

Green Ink
congratulates
Hailey's Hope
for making
a difference
in so many lives



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