



ALL INFANTS ARE NOT THE SAME



SYNAGIS® in the NICU:

CRITICAL PROTECTION AGAINST SEVERE RSV DISEASE

Preterm infants 29 to 35 wGA may be hospitalized for RSV soon after birth

82% of RSV hospitalizations occur within 60 days of birth hospitalization discharge²

Very preterm infants* <3 months of age are at high risk for ICU admission and IMV

69% required ICU admission²
41% required IMV²

Please see additional Important Safety Information throughout and on page 8. Please click here for full Prescribing Information for SYNAGIS, including Patient Information.

INDICATION

SYNAGIS, 50 mg and 100 mg for injection, is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients:

- with a history of premature birth (≤ 35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season
- with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season
- with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season

LIMITATIONS OF USE

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

CONTRAINDICATIONS

Previous significant hypersensitivity reaction to SYNAGIS.

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions: Anaphylaxis and anaphylactic shock (including fatal cases) and other severe acute hypersensitivity reactions have been reported. Permanently discontinue SYNAGIS and administer appropriate medication if such reactions occur.

*Birth prior to 37 wGA is defined as preterm. Birth from 28 to 32 wGA is considered very preterm, while birth <28 wGA is considered extremely preterm.^{3,4}

ICU=intensive care unit; IMV=invasive mechanical ventilation; NICU=neonatal intensive care unit; RSV=respiratory syncytial virus; wGA=weeks gestational age.

SYNAGIS®
PALIVIZUMAB



FOR OVER 25 YEARS,
PROTECTING MILLIONS OF THE
HIGHEST RISK INFANTS FROM RSV¹

REFERENCES



RSVH SOON AFTER BIRTH

ICU ADMISSION AND MECHANICAL VENTILATION

DOSE BEFORE DISCHARGE

CONTINUITY OF CARE

NICU DISCHARGE: 3 STEPS

IMPORTANT SAFETY INFORMATION

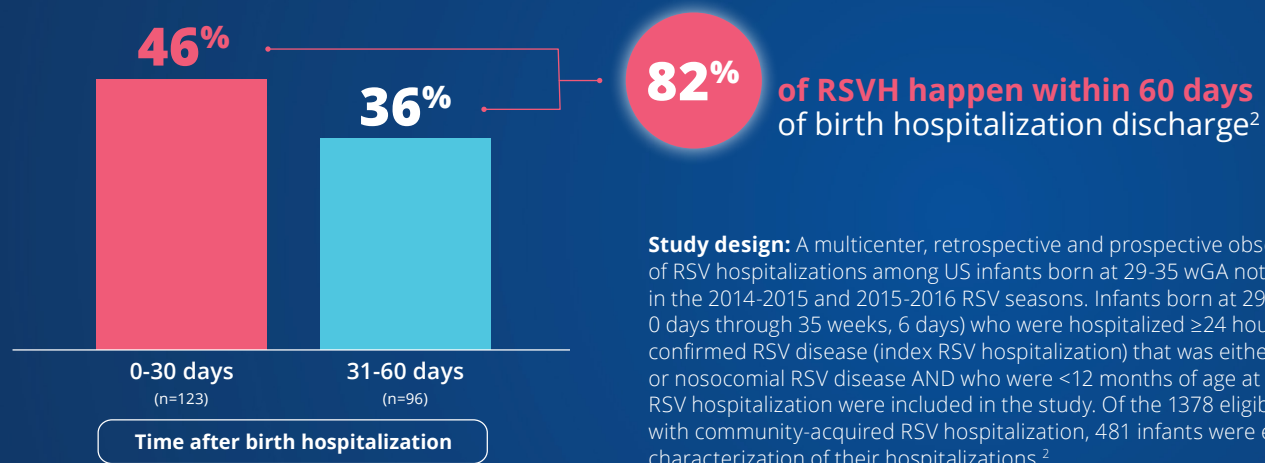


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For preterm infants 29 to 35 wGA

RSV HOSPITALIZATIONS OCCUR SOON AFTER BIRTH^{2*}

Percentage of RSV hospitalizations occurring within 30 and 60 days after discharge from birth hospitalization^{2†}



Study design: A multicenter, retrospective and prospective observational study of RSV hospitalizations among US infants born at 29-35 wGA not receiving SYNAGIS[®] in the 2014-2015 and 2015-2016 RSV seasons. Infants born at 29-35 wGA (29 weeks, 0 days through 35 weeks, 6 days) who were hospitalized ≥24 hours for laboratory-confirmed RSV disease (index RSV hospitalization) that was either community-acquired or nosocomial RSV disease AND who were <12 months of age at the time of index RSV hospitalization were included in the study. Of the 1378 eligible preterm infants with community-acquired RSV hospitalization, 481 infants were enrolled for in-depth characterization of their hospitalizations.²

*Based on a subgroup analysis of the SENTINEL1 study.

[†]Among infants discharged from their birth hospitalization from November 1 through March 31 (n=267). Among infants in the days since birth hospitalization discharge groups (61-90 [n=31], 91-120 [n=12], 121-150 [n=4], and 151-180 [n=1]), the proportion of infants hospitalized for RSV disease was 12%, 4%, 1%, and <1%, respectively.^{2,5}

Please see additional Important Safety Information throughout and on page 8. Please click here for full Prescribing Information for SYNAGIS, including Patient Information.

RSV=respiratory syncytial virus; RSVH=respiratory syncytial virus hospitalization; wGA=weeks gestational age.

IMPORTANT SAFETY INFORMATION (continued)

Coagulation Disorders: SYNAGIS should be given with caution to children with thrombocytopenia or any coagulation disorder.

RSV Diagnostic Test Interference: Palivizumab may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays.

Serious Adverse Reactions: The most common serious adverse reactions occurring with SYNAGIS are anaphylaxis and other acute hypersensitivity reactions.

Most Common Adverse Reactions: The most common adverse reactions are fever and rash.

Postmarketing Experience: Severe thrombocytopenia and injection site 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.

These are not all the possible risks associated with SYNAGIS.

[Please click here for full Prescribing Information for SYNAGIS, including Patient Information.](#)

To report suspected adverse reactions, contact Sobi North America at 1-866-773-5274 or the FDA at 1-800-FDA-1088.

REFERENCES



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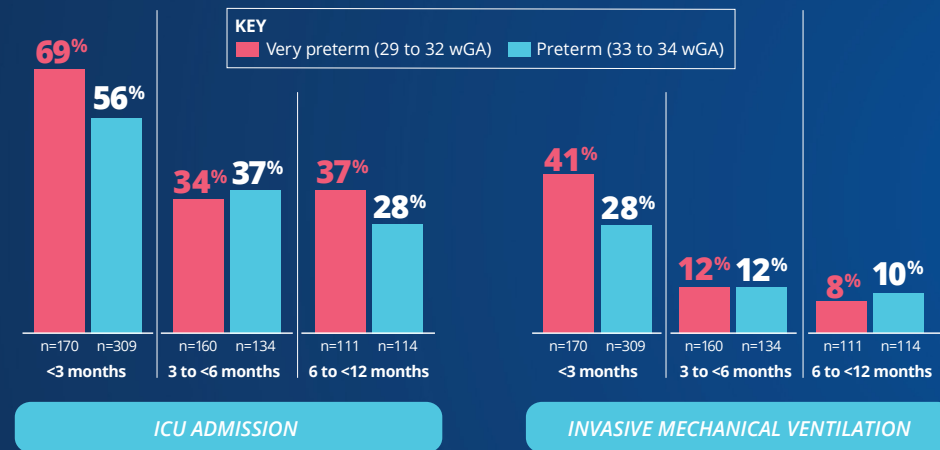
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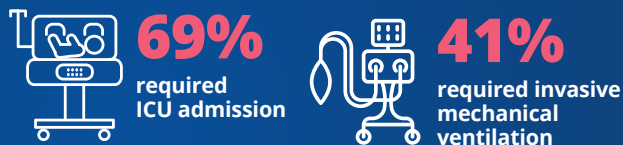
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RSV LEADS TO HIGH RATES OF ICU ADMISSION AND INVASIVE MECHANICAL VENTILATION²

RISK BY GESTATIONAL AGE



AMONG VERY PRETERM INFANTS <3 MONTHS OF AGE



Earlier gestational age and younger chronological age were associated with high rates of ICU admission and need for invasive mechanical ventilation²

ICU=intensive care unit; RSV=respiratory syncytial virus.

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LIMITATIONS OF USE

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

CONTRAINDICATIONS

Previous significant hypersensitivity reaction to SYNAGIS.

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions: Anaphylaxis and anaphylactic shock (including fatal cases) and other severe acute hypersensitivity reactions have been reported. Permanently discontinue SYNAGIS and administer appropriate medication if such reactions occur.

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SYNAGIS® in the NICU: DOSE BEFORE DISCHARGE

AAP CLINICAL PRACTICE GUIDANCE

“ Hospitalized infants at risk for severe RSV infection should receive prophylaxis **48 to 72 hours before discharge** and **every 30 days** until the end of the season.⁶ ”

—The American Academy of Pediatrics

In preterm infants ≤35 wGA initiated on SYNAGIS as outpatients, average time to receipt of first dose was 35 days post-NICU discharge⁷

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AAP=American Academy of Pediatrics; NICU=neonatal intensive care unit; RSV=respiratory syncytial virus; wGA=weeks gestational age.

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ALL INFANTS ARE NOT THE SAME

CONTINUITY OF CARE HELPS ENSURE THE HIGHEST RISK INFANTS REMAIN PROTECTED

YEAR-ROUND TRANSITION OF CARE IS CRITICAL

IN SEASON

- ✓ Reduces the time for an infant to receive the first SYNAGIS[®] dose in the office
- ✓ Initiates coordination between Sobi representative and outpatient provider to ensure continuity of care

OUT OF SEASON

- ✓ Tracks infants born out of RSV season who may need SYNAGIS at the start of the upcoming season
- ✓ Tracks children with BPD and HS-CHD who remain at high risk during their second RSV season^{8,9}
- ✓ Allows for early identification of patients and quick initiation of SYNAGIS once RSV begins circulating

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BPD=bronchopulmonary dysplasia; HS-CHD=hemodynamically significant congenital heart disease; RSV=respiratory syncytial virus.

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NICU DISCHARGE: 3 STEPS

1 Dose before discharge per AAP guidance

2 Initiate the SYNAGIS® transition of care process to ensure continuity of care

- Add the appropriate ICD-10 codes to the patient's EHR
- Forward the postdischarge summary



EHR Patient Identification Slim Jim



SYNAGIS Coding Resource

3 Follow up with caregivers

- Provide the discharge folder
- Remind caregivers to schedule their baby's next dose within 28 to 30 days of the previous dose



Discharge Folder



SYNAGIS®—OVER 25 YEARS OF REAL-WORLD EVIDENCE
Proven protection against severe RSV disease¹⁰

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AAP=American Academy of Pediatrics; EHR=electronic health record; ICD-10=International Classification of Diseases, Tenth Revision; NICU=neonatal intensive care unit; RSV=respiratory syncytial virus.

IMPORTANT SAFETY INFORMATION (continued)

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1. Data on file. Sobi, Inc. Two million patients as of June 30, 2022.
2. Anderson EJ, DeVincenzo JP, Simões EAF, et al. SENTINEL1: Two-season study of respiratory syncytial virus hospitalizations among US infants born at 29 to 35 weeks' gestational age not receiving immunoprophylaxis. *Am J Perinatol*. 2020;37(4):421-429.
3. Preterm birth. World Health Organization. Published May 10, 2023. Accessed May 24, 2023. <https://www.who.int/news-room/fact-sheets/detail/preterm-birth>
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5. Data on file. Sobi, Inc. 2017.
6. American Academy of Pediatrics Committee on Infectious Diseases; American Academy of Pediatrics Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics*. 2014;134(2):415-420.
7. Data on file. Sobi, Inc. 2015.
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9. Friedman D, Fryzek J, Jiang X, Bloomfield A, Ambrose CS, Wong PC. Respiratory syncytial virus risk in the second year of life by specific congenital heart disease diagnoses. *PLoS ONE*. 2017;12(3):e0172512. doi:10.1371/journal.pone.0172512
10. SYNAGIS (palivizumab) [prescribing information]. Waltham, MA: Sobi, Inc. 2021.

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SYNAGIS®—OVER 25 YEARS OF REAL-WORLD EVIDENCE
Proven protection against severe RSV disease¹⁰

- **SYNAGIS is a monoclonal antibody** with a monthly dosing regimen that allows HCPs to dose-adjust based on¹⁰:
 - An infant’s weight as they grow
 - The unpredictable timing and duration of the RSV season
- Each SYNAGIS dose provides enough **antibodies to protect the highest risk infants** for 28 to 30 days¹⁰

IDENTIFY YOUR HIGHEST RISK INFANTS
AND PROVIDE THEM WITH PROTECTION AGAINST SEVERE RSV DISEASE WITH SYNAGIS



**FOR OVER 25 YEARS,
PROTECTING MILLIONS OF THE
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Colorado prescribers, please click here for additional information.

All imagery is for illustrative purposes only.

RSV=respiratory syncytial virus.



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