

FOR INFANTS RECEIVING RSV-IP,
THE AMERICAN ACADEMY OF PEDIATRICS RECOMMENDS:
DOSE SYNAGIS 48-72 HOURS BEFORE DISCHARGE DURING RSV SEASON¹

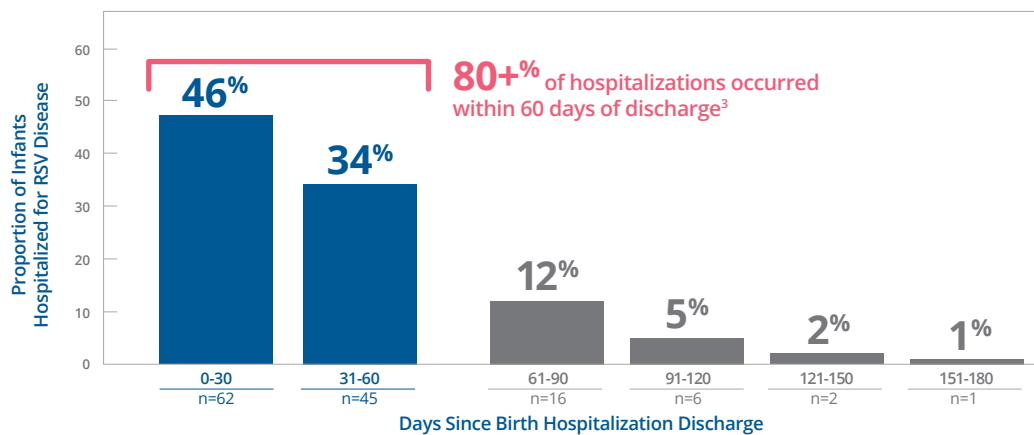


SYNAGIS in the NICU

A Critical Line of Defense Against Severe RSV



In a subgroup analysis of the SENTINEL1 study*^{2,3}
46% of RSV hospitalizations occurred within 30 days of birth discharge



*Among infants discharged from their birth hospitalization from November 1 through March 31 (n = 267).³

SENTINEL1 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 1,378 eligible preterm infants with community-acquired RSV hospitalization, 481 infants were enrolled for in-depth characterization of their hospitalizations.^{2,3}

The SENTINEL1 study demonstrated
Premature infants hospitalized with RSV who did not receive SYNAGIS experienced significant morbidity³

69% of infants 29-32 wGA and <3 months CA required ICU admission³

41% of infants 29-32 wGA and <3 months CA required invasive mechanical ventilation³

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.

IMPORTANT SAFETY INFORMATION

- SYNAGIS is contraindicated in children who have had a previous significant hypersensitivity reaction to SYNAGIS

CA=chronological age; ICU=intensive care unit; NICU=neonatal intensive care unit; RSV-IP=RSV immunoprophylaxis; wGA=weeks gestational age.

Please see additional Important Safety Information on back and accompanying full Prescribing Information for SYNAGIS, including Patient Information.



DOSE BEFORE DISCHARGE

Protection From Severe RSV Starts in the NICU



In premature infants ≤ 35 wGA initiated on SYNAGIS as outpatients during RSV season, Average time to receipt of first dose was **35 days post-NICU discharge**⁴

Effective Transitions of Care involve a year-round commitment by you and your team to ensure

- Timely initiation of the first post-discharge dose
- Continued protection of high-risk infants from the NICU to outpatient setting

The **SYNAGIS CONNECT™** program helps coordinate seamless transition of care.

For more information, call 1-833-SYNAGIS (1-833-796-2447) or visit SYNAGISHCP.com



IMPORTANT SAFETY INFORMATION (continued)

- Cases of anaphylaxis and anaphylactic shock, including fatal cases, have been reported following initial exposure or re-exposure to SYNAGIS. Other acute hypersensitivity reactions, which may be severe, have also been reported on initial exposure or re-exposure to SYNAGIS. The relationship between these reactions and the development of antibodies to SYNAGIS is unknown. If a significant hypersensitivity reaction occurs with SYNAGIS, its use should be permanently discontinued. If a mild hypersensitivity reaction occurs, clinical judgment should be used regarding cautious readministration of SYNAGIS
- As with any intramuscular injection, SYNAGIS should be given with caution to children with thrombocytopenia or any coagulation disorder
- Palivizumab may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays
- Adverse reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. In post-marketing reports, cases of severe thrombocytopenia (platelet count $< 50,000$ /microliter) and injection site reactions have been reported

DOSING

The recommended dose of SYNAGIS is 15 mg/kg of body weight given monthly by intramuscular injection. The first dose of SYNAGIS should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season. Children who develop an RSV infection should continue to receive monthly doses throughout the RSV season.

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

Please see accompanying full Prescribing Information for SYNAGIS, including Patient Information.

NICU=neonatal intensive care unit; RSV=respiratory syncytial virus; wGA=weeks gestational age.

References: 1. 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. 2. Data on file, Sobi, Inc. 3. Anderson EJ, DeVincenzo JP, Simões EA, et al. SENTINEL1: two-season study of respiratory syncytial virus hospitalizations among U.S. infants born at 29 to 35 weeks' gestational age not receiving immunoprophylaxis. *Am J Perinatol*. 2020;37(4):421-429. 4. Data on file, Sobi, Inc.



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