



# SYNAGIS is NOT a vaccine

**SYNAGIS is the only FDA-approved monoclonal antibody to help protect high-risk infants against RSV<sup>1</sup>**

- SYNAGIS delivers antibodies that are immediately available to fight RSV<sup>1,2</sup>
- Unlike vaccines, antibodies do not provide long-lasting immunity.<sup>2</sup> SYNAGIS needs to be given each month (every 28-30 days) throughout the RSV season to provide continuous protection against RSV<sup>1,3-5</sup>
  - Noncompliance puts infants at increased risk for RSV-related hospitalizations<sup>3</sup>

## 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 ( $\leq 35$  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

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



# Protect your high-risk infants Dose with SYNAGIS

- **SYNAGIS** does not induce endogenous anti-RSV antibodies and must be administered every 28-30 days<sup>1</sup>
- High-risk infants should receive **monthly doses** of SYNAGIS throughout the RSV season, which typically runs from late fall through spring<sup>1,4,5\*</sup>

## Get patients STARTED ON SYNAGIS

**SYNAGIS CONNECT™** is a patient support program created by Sobi to provide individualized support to help appropriate patients get access to SYNAGIS.

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



Disclaimer: Patients will not receive a physical copay card. Eligibility requirements apply.

## 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.**

RSV=respiratory syncytial virus.

\*RSV season can vary by geography and from year to year.<sup>4</sup>

**References:** 1. SYNAGIS [package insert]. Gaithersburg, MD: MedImmune. 2. Delves PJ, et al. Vaccines. In: *Roitt's Essential Immunology*. 11<sup>th</sup> ed. Malden, MA: Blackwell Publishing; 2006:287-311. 3. Makari D, Checchia PA, DeVincenzo J. Rationale for full-season dosing for passive antibody prophylaxis of respiratory syncytial virus. *Hum Vaccin Immunother*. 2014;10(3): 607-614. 4. Centers for Disease Control and Prevention. RSV transmission. Last reviewed June 26, 2018. Accessed March 6, 2020. <https://www.cdc.gov/rsv/about/transmission.html> 5. 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.



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