ALL INFANTS ARE NOT THE SAME

In children ≤24 months with HS-CHD,

SYNAGIS® significantly reduced RSV hospitalizations[2,3]*

Infants <6 months of age with CHD are at greatest risk for severe RSV disease

Children 6 to 24 months remain at high risk:
~4x-5x rate of RSV hospitalizations as compared to full-term infants[4]

Once hospitalized, infants with CHD are at high risk for increased RSVH severity

~19%-26% mechanical ventilation use[5]
up to 1.5% inpatient mortality[5]

Please see additional Important Safety Information throughout and on page 7. 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.

*In a pivotal trial of children ≤24 months with HS-CHD, the RSV hospitalization rate was 5.3% in the SYNAGIS group and 9.7% in the placebo group (P=0.003).[2,3]

CHD=congenital heart disease; HS-CHD=hemodynamically significant congenital heart disease; RSV=respiratory syncytial virus; RSVH=respiratory syncytial virus hospitalization.

SYNAGIS®
PALIVIZUMAB

FOR OVER 25 YEARS,
PROTECTING MILLIONS OF THE HIGHEST RISK INFANTS FROM RSV[1]

REFERENCES

ALL INFANTS ARE NOT THE SAME

In children with CHD,

RSVH RATES ARE HIGHEST BEFORE 6 MONTHS WHILE INCIDENCE RATIOS INCREASE THROUGH 2 YEARS[4]

CHRONOLOGICAL AGE	HOSPITALIZATIONS (per 1000 children)		INCIDENCE RATIOS FOR CHILDREN WITH CHD (compared with full-term infants*)
	FULL TERM	CHD	
<6 months	44.1	120.8	**~3x greater**
6 to <12 months	15.0	63.5	**~4x greater**
12 to <24 months	3.7	18.2	**~5x greater**

CHILDREN WITH CHD **accounted for ~73% to 83% of hospitalizations**[4]

Please see additional Important Safety Information throughout and on page 7. Please click here for full Prescribing Information for SYNAGIS, including Patient Information.

Study design: A retrospective cohort study analyzed hospitalizations for RSV-related illness in children <3 years of age enrolled in the Tennessee Medicaid system from July 1989 through June 1993. Rates were based on hospitalizations per year per 1000 children.[4]

*The reference group comprised full-term (≥37 wGA) infants without BPD, CHD, or certain other specific medical conditions.

BPD=bronchopulmonary dysplasia; CHD=congenital heart disease; 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.

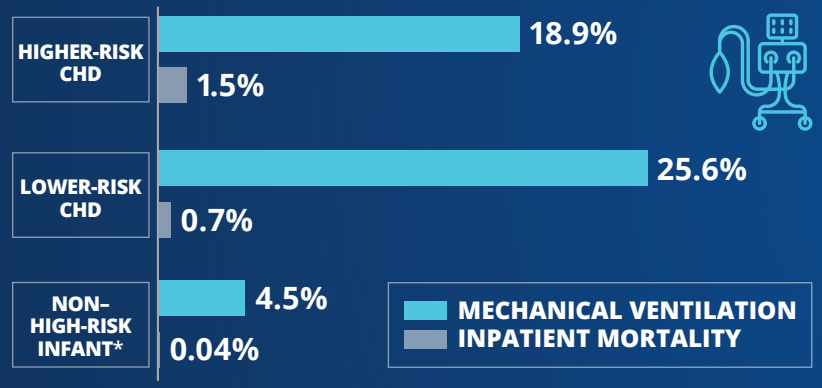
REFERENCES

ALL INFANTS ARE NOT THE SAME

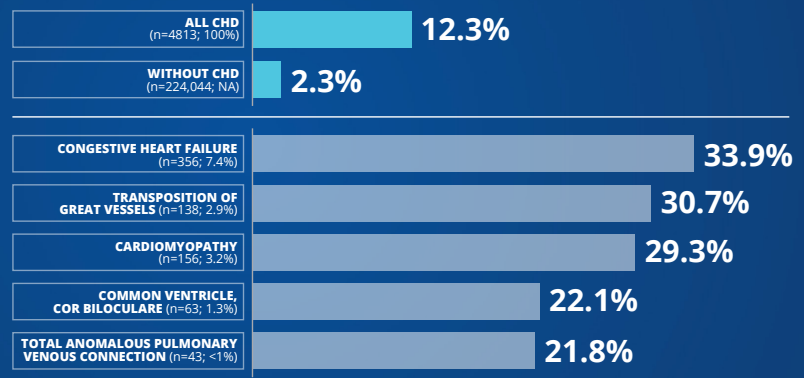
Once hospitalized with RSV, children with CHD are at

SIGNIFICANT RISK FOR RSVH SEVERITY[5,6]

INFANTS WITH CHD IN THE FIRST YEAR OF LIFE
had increased rates of mechanical ventilation and inpatient mortality[5]



CHILDREN WITH CERTAIN TYPES OF CHD IN THE SECOND YEAR OF LIFE
had the highest rates of mechanical ventilation[6†]



Please see additional Important Safety Information throughout and on page 7. Please click here for full Prescribing Information for SYNAGIS, including Patient Information.

Study design: A retrospective review of annual RSV hospitalization rates among 756,975 children with CHD using the Kids' Inpatient Database (KID) from 4100 hospitals between 1997 and 2012 and implementing ICD-9 diagnostic codes (079.6, 466.11, 480.1). The CHD population was stratified into higher- and lower-risk categories based on the incidence of RSV for individual ICD-9 diagnostic codes. If a code was associated with a low- or high-risk infant, that infant was classified as high risk.[5]

Study design: A retrospective review of the National Inpatient Sample database assessing RSV hospitalization (ICD-9 480.1, 466.11, or 079.6) rates among 1,168,886 children 12-23 months of age with CHD compared to 65,333,543 children without CHD from 1997 to 2013.[6]

*The non–high-risk group comprised infants without CHD, CLD, Down syndrome without CLD, congenital airway abnormalities, cystic fibrosis with pulmonary manifestations, neuromuscular disease, HIV, immunodeficiency, and other genetic metabolic musculoskeletal conditions.

†Chart shows the top 5 types of CHD by percentage of patients who required mechanical ventilation during hospitalization for RSV. The population figures and percentages along the y-axis show the number and percentage of patients with each type of CHD.

CHD=congenital heart disease; CLD=chronic lung disease; HIV=human immunodeficiency virus; ICD-9=International Classification of Diseases, Ninth Revision; RSV=respiratory syncytial virus; RSVH=respiratory syncytial virus hospitalization; wGA=weeks gestational age.

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

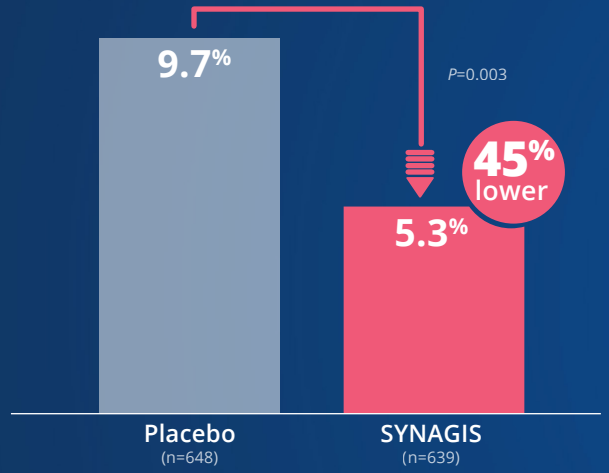
Hypersensitivity Reactions: Anaphylaxis and anaphylactic shock (including fatal cases) and other severe acute hypersensitivity reactions have been reported. Permanently discontinue SYNAGIS and administer appropriate medication if such reactions occur.

REFERENCES

ALL INFANTS ARE NOT THE SAME

In children ≤24 months of age with HS-CHD,

SYNAGIS® SIGNIFICANTLY REDUCED RSV HOSPITALIZATIONS BY 45%[2,3]



TRIAL INCLUDED MORE THAN 1280 CHILDREN WITH HS-CHD

MOST FREQUENTLY REPORTED ADVERSE EVENTS

that were judged to be potentially related to study drug[3]

	Placebo (n=648)	SYNAGIS (n=639)
Fever	23.9%	27.1%
Infection	2.9%	5.6%
Injection-site reaction	2.2%	3.4%
Upper respiratory infection	46.1%	47.4%
Conjunctivitis	9.3%	11.3%
Arrhythmia*	1.7%	3.1%
Cyanosis*	6.9%	9.1%

- No child had study drug discontinued for a related adverse event[3]
- Few adverse events were reported at an absolute incidence ≥1% higher in the SYNAGIS group than in the placebo group[3]
- In the pivotal trials combined, adverse reactions occurring at a rate of ≥10% and ≥1% more frequently with SYNAGIS than with placebo were fever and rash[2]

Please see additional Important Safety Information throughout and on page 7. Please click here for full Prescribing Information for SYNAGIS, including Patient Information.

Study design: A randomized, double-blind, placebo-controlled trial of 1287 children with hemodynamically significant CHD randomly assigned 1:1 to receive 5 monthly intramuscular injections of SYNAGIS 15 mg/kg or placebo. The study was conducted at 76 centers in the United States (n=47), Canada (n=6), Sweden (n=3), Germany (n=4), Poland (n=6), France (n=4), and the United Kingdom (n=6). Results may not be generalizable to a US population.[3]

*None of the events reported as arrhythmia and one event reported as cyanosis (placebo recipient) were judged related to the study drug.[3]

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

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.

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These are not all the possible risks associated with SYNAGIS.

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REFERENCES

ALL INFANTS ARE NOT THE SAME

SYNAGIS® SIGNIFICANTLY REDUCED RSVH SEVERITY[3]*

SECONDARY ENDPOINTS

56%
fewer total days of RSV-related hospitalizations
(per 100 children: 129 days for placebo vs 57.4 days with SYNAGIS; *P*=0.003)

73%
fewer total days with increased supplemental oxygen
(per 100 children: 101.5 days for placebo vs 27.9 days with SYNAGIS; *P*=0.014)

Please see additional Important Safety Information throughout and on page 7. Please click here for full Prescribing Information for SYNAGIS, including Patient Information.

*The placebo and SYNAGIS groups did not show statistically significant differences in incidence of RSV-related ICU admissions (3.7% vs 2.0%, *P*=0.094), total days of RSV-related ICU stays per 100 children (71.2 days vs 15.9 days, *P*=0.80), incidence of RSV-related mechanical ventilation (2.2% vs 1.3%, *P*=0.282), or total days of RSV-related mechanical ventilation per 100 children (54.7 days vs 6.5 days, *P*=0.224).

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

INDICATION

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LIMITATIONS OF USE

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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.

REFERENCES

References:

1. Data on file. Sobi, Inc. Two million patients as of June 30, 2022.
2. SYNAGIS (palivizumab) [prescribing information]. Waltham, MA: Sobi, Inc. 2021.
3. Feltes TF, Cabalka AK, Meissner HC, et al. Palivizumab prophylaxis reduces hospitalization due to respiratory syncytial virus in young children with hemodynamically significant congenital heart disease. *J Pediatr*. 2003;143(4):532-540.
4. Boyce TG, Mellen BG, Mitchel EF Jr, Wright PF, Griffin MR. Rates of hospitalization for respiratory syncytial virus infection among children in Medicaid. *J Pediatr*. 2000;137(6):865-870.
5. Doucette A, Jiang X, Fryzek J, Coalson J, McLaurin K, Ambrose CS. Trends in respiratory syncytial virus and bronchiolitis hospitalization rates in high-risk infants in a United States nationally representative database, 1997-2012. *PLoS ONE*. 2016;11(4):e0152208. doi:10.1371/journal.pone.0152208
6. 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

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ALL INFANTS ARE NOT THE SAME

SYNAGIS®—OVER 25 YEARS OF REAL-WORLD EVIDENCE
Proven protection against severe RSV disease[2]

- SYNAGIS is a monoclonal antibody with a monthly dosing regimen that allows HCPs to dose-adjust based on[2]:
  - — 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 days[2]

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

SYNAGIS®
PALIVIZUMAB

FOR OVER 25 YEARS,
PROTECTING MILLIONS OF THE HIGHEST RISK INFANTS FROM RSV[1]

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Colorado prescribers, please click here for additional information.

All imagery is for illustrative purposes only.

HCP=healthcare provider; RSV=respiratory syncytial virus.

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REFERENCES