

Dosing Guide

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.

Please see additional Important Safety Information throughout. [Click here for full Prescribing Information for SYNAGIS, including Patient Information.](#)

How Supplied



SYNAGIS® (palivizumab) is supplied as a liquid formulation for intramuscular (IM) injection.¹

- Single-use vials
- Preservative-free
- Sterile solution
- 50-mg/0.5-mL box and vial have pink stripe
- 100-mg/1-mL box and vial have blue stripe

Storage¹

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.

Preparation¹

- Using aseptic techniques, attach a sterile needle to a sterile syringe
- Remove the flip top from the vial and clean the rubber stopper with 70% isopropyl alcohol or equivalent
- **DO NOT dilute the product**
- **DO NOT shake vial**
- Using the needle, withdraw the appropriate volume of SYNAGIS for your patient
- SYNAGIS does not contain a preservative and should be administered immediately after withdrawal from vial
- SYNAGIS is supplied in single-use vials. DO NOT re-enter the vial. Discard any unused portion

For additional information and a helpful dosing calculator, visit [SYNAGIS.com](https://www.synagis.com).

Please see additional Important Safety Information throughout. [Click here for full Prescribing Information for SYNAGIS, including Patient Information.](#)

Administration¹

SYNAGIS® (palivizumab) should be administered in a dose of 15 mg/kg via IM injection 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.

Preferred location for injection



Once administered, notify the specialty pharmacy to initiate refill process for next dose, if needed.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Dosing¹

The recommended dose of SYNAGIS[®] (palivizumab) is 15 mg/kg of body weight given monthly by IM injection. The first dose of SYNAGIS should be administered prior to commencement of the respiratory syncytial virus (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.

Dosing Table^{1,†}

To calculate the dose per month, multiply the patient weight (in kg) by 15 mg/kg and divide by 100 mg/mL (1.0 kg=2.20462262 lb). Injection volume over 1 mL should be given as a divided dose.

(Patient weight (kg) x 15 mg/kg) ÷ 100 mg/mL

Patient weight	Dose per month	Patient weight	Dose per month
1.2 kg (2 lb, 10 oz)	0.18 mL	5.8 kg (12 lb, 13 oz)	0.87 mL
1.4 kg (3 lb, 1 oz)	0.21 mL	6.0 kg (13 lb, 4 oz)	0.90 mL
1.6 kg (3 lb, 8 oz)	0.24 mL	6.2 kg (13 lb, 11 oz)	0.93 mL
1.8 kg (3 lb, 15 oz)	0.27 mL	6.4 kg (14 lb, 2 oz)	0.96 mL
2.0 kg (4 lb, 7 oz)	0.30 mL	6.6 kg (14 lb, 9 oz)	0.99 mL
2.2 kg (4 lb, 14 oz)	0.33 mL	6.8 kg (15 lb, 0 oz)	1.02 mL
2.4 kg (5 lb, 5 oz)	0.36 mL	7.0 kg (15 lb, 7 oz)	1.05 mL
2.6 kg (5 lb, 12 oz)	0.39 mL	7.2 kg (15 lb, 14 oz)	1.08 mL
2.8 kg (6 lb, 3 oz)	0.42 mL	7.4 kg (16 lb, 5 oz)	1.11 mL
3.0 kg (6 lb, 10 oz)	0.45 mL	7.6 kg (16 lb, 12 oz)	1.14 mL
3.2 kg (7 lb, 1 oz)	0.48 mL	7.8 kg (17 lb, 3 oz)	1.17 mL
3.4 kg (7 lb, 8 oz)	0.51 mL	8.0 kg (17 lb, 10 oz)	1.20 mL
3.6 kg (7 lb, 15 oz)	0.54 mL	8.2 kg (18 lb, 1 oz)	1.23 mL
3.8 kg (8 lb, 6 oz)	0.57 mL	8.4 kg (18 lb, 8 oz)	1.26 mL
4.0 kg (8 lb, 13 oz)	0.60 mL	8.6 kg (18 lb, 15 oz)	1.29 mL
4.2 kg (9 lb, 4 oz)	0.63 mL	8.8 kg (19 lb, 6 oz)	1.32 mL
4.4 kg (9 lb, 11 oz)	0.66 mL	9.0 kg (19 lb, 13 oz)	1.35 mL
4.6 kg (10 lb, 2 oz)	0.69 mL	9.2 kg (20 lb, 5 oz)	1.38 mL
4.8 kg (10 lb, 9 oz)	0.72 mL	9.4 kg (20 lb, 12 oz)	1.41 mL
5.0 kg (11 lb, 0 oz)	0.75 mL	9.6 kg (21 lb, 3 oz)	1.44 mL
5.2 kg (11 lb, 7 oz)	0.78 mL	9.8 kg (21 lb, 10 oz)	1.47 mL
5.4 kg (11 lb, 14 oz)	0.81 mL	10.0 kg (22 lb, 1 oz)	1.50 mL
5.6 kg (12 lb, 6 oz)	0.84 mL	10.2 kg (22 lb, 8 oz)	1.53 mL

*In most of the United States, the RSV season starts in the fall and lasts through the spring; however, it may vary each year and by geographic region.

†Information here has been provided as a guide only and is not intended to be a substitute for or an influence on the independent judgment of the healthcare professional.

Please see additional Important Safety Information throughout. [Click here for full Prescribing Information for SYNAGIS, including Patient Information.](#)



SYNAGIS CONNECT®

SYNAGIS CONNECT is a free program created by Sobi to provide individualized support to help eligible patients get access to SYNAGIS® (palivizumab). **SYNAGIS CONNECT** can help parents and caregivers understand the treatment process and their financial options, educate providers in navigating insurance and reimbursement questions, and assist in the coordination of care and the specialty pharmacy process.

In order for the patient and their caregiver to take advantage of this program, consent/authorization must be obtained.

SYNAGIS CONNECT representatives can answer questions related to



Insurance verification



Identifying prescription coverage



Claims and appeal process support



Patient out-of-pocket costs



Affordability programs (based on eligibility)

SYNAGIS
CONNECT®



Call **SYNAGIS CONNECT** at **1-833-SYNAGIS (1-833-796-2447)** for more information or visit [SYNAGIS.com](https://www.synagis.com) for additional resources.

Please see additional Important Safety Information throughout. [Click here for full Prescribing Information for SYNAGIS, including Patient Information.](#)

Reference: 1. SYNAGIS [prescribing information]. Waltham, MA: Sobi, Inc.

Colorado prescribers, please [click here](#) for more information.

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