SYNAGIS®
PALIVIZUMAB

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

IMPORTANT SAFETY INFORMATION

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

Please see Important Safety Information throughout and accompanying 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

Storage[1]

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.

Preparation[1]

- 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

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Administration[1]

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

- 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

LIMITATIONS OF USE

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

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Dosing[1]

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 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

*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.

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SYNAGIS CONNECT™

SYNAGIS CONNECT™ is a free program created by Sobi to provide individualized support to help patients get access to SYNAGIS® (palivizumab). SYNAGIS CONNECT™ can help parents and caregivers understand the treatment process and their financial options, support 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** for additional resources.

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

Reference: 1. SYNAGIS [prescribing information]. Gaithersburg, MD: MedImmune; May 2017.

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