SYNAGIS®
PALIVIZUMAB

Dosing Guide

Indication[1]

SYNAGIS® is indicated for the prevention of serious lower respiratory tract disease requiring hospitalisation caused byrespiratory syncytial virus (RSV) in children at high risk for RSV disease:

- Children born at 35 weeks of gestation or less and less than 6 months of age at the onset of the RSV season.
- Children less than 2 years of age and requiring treatment for bronchopulmonary dysplasia within the last 6 months.
- Children less than 2 years of age and with haemodynamically significant congenital heart disease.

How is it Supplied

SYNAGIS® (palivizumab) is supplied as a solution for injection[1]

- Single-use vials
- Preservative-free
- 50-mg/0.5-mL vial
- 100-mg/1-mL vial

Storage[1]

Store in a refrigerator (2°C to 8°C).Do not freeze. Keep the vial in the carton in order to protect from light.

Preparation[1]

- Do not mix the SYNAGIS® liquid and lyophilised formulations.
- Do not dilute the product.
- Do not shake the vial.
- Both the 0.5 ml and 1 ml vials contain an overfill to allow the withdrawal of 50 mg or 100 mg, respectively.
- To administer, remove the tab portion of the vial cap and clean the stopper with 70 % ethanol or equivalent. Insert the needle into the vial and withdraw into the syringe an appropriate volume of solution.
- SYNAGIS® solution for injection does not contain a preservative, is for single use and should be administered immediately after drawing the dose into the syringe.
- Any unused product or waste material should be disposed of in accordance with local requirements.

Administration[1]

SYNAGIS® is administered intramuscularly, 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. The injection should be given using standard aseptic technique.

Preferred location for injection

Important Safety Information[1]

- SYNAGIS® is contraindicated in children with hypersensitivity to the active substance or to any of the excipients or to other humanised monoclonal antibodies
- Allergic reactions including very rare cases of anaphylaxis and anaphylactic shock have been reported following SYNAGIS® administration. In some cases, fatalities have been reported. Medicinal products for the treatment of severe hypersensitivity reactions, including anaphylaxis and anaphylactic shock, should be available for immediate use following administration of SYNAGIS®.
- As with any intramuscular injection, SYNAGIS® should be given with caution to patients with thrombocytopaenia or any coagulation disorder.
- SYNAGIS® may interfere with immune-based RSV diagnostic tests, such as some antigen detection based assays.
- The most serious adverse reactions occurring with SYNAGIS® are anaphylaxis and other acute hypersensitivity reactions. Common adverse reactions occurring with SYNAGIS® are fever, rash, and injection site reaction.

Adverse reactions* with SYNAGIS in clinical studies and postmarketing reports in paediatric patients[1]

MedDRA System Organ Class	Frequency	Adverse Reactions
Blood and lymphatic system disorders	Uncommon	Thrombocytopaenia†
Immune system disorders	Not known	Anaphylaxis, anaphylactic shock (in some cases, fatalities have been reported) †‡
Nervous system disorders	Uncommon	Convulsion †
Respiratory, thoracic and mediastinal disorders	Common	Apnoea †
Skin and subcutaneous tissue disorders	Very common	Rash
	Uncommon	Urticaria †
General disorders and administrative site conditions	Very common	Pyrexia
	Common	Injection site reaction

*Adverse reactions both clinical and laboratory, are displayed by system organ class and frequency (very common ≥ 1/10; common ≥ 1/100 to < 1/10; uncommon ≥ 1/1,000 to < 1/100; rare ≥ 1/10,000 to <1/1,000) in studies conducted in premature and bronchopulmonary dysplasia paediatric patients, and paediatric congenital heart disease patients[1]. †ADRs identified from post-marketing surveillance[1]. ‡Frequency of anaphylaxis is unknown and frequency for acute hypersensitivity reactions is very common (1/10) [1]

Dosing[1]

The recommended dose of SYNAGIS® is 15 mg/kg of body weight given monthly by IM injection. **Where possible, the first dose should be administered prior to commencement of the RSV season. Subsequent doses should be administered monthly throughout the RSV season. To reduce risk of rehospitalisation, it is recommended that children receiving SYNAGIS® who are hospitalised with RSV continue to receive monthly doses of SYNAGIS® for the duration of the RSV season.**

The efficacy of SYNAGIS® at doses other than 15 mg per kg or of dosing differently from 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.

ADR, adverse drug reaction; MedDRA, medical dictionary for regulatory activities; RSV, respiratory syncytial virus

Reference: 1. SYNAGIS®. Summary of Product Characteristics.

Please reach out to AstraZeneca for Full Prescribing Information.

For Gulf:

For Reporting Adverse events and/or Product Quality Complains: Website: https://contactazmedical.astrazeneca.com
E-mail: Patientsafety-azgulf@astrazeneca.com Call AstraZeneca FZ LLC land line: +97143624888.

For Medical information Enquires : Website: https://contactazmedical.astrazeneca.com
E-mail: gulf-medicalinfo@astrazeneca.com; Call AstraZeneca FZ LLC land line: +97143624888

For Saudi:

For Medical information please send an email to medinfo-ksa@astrazeneca.com
For AE reporting send email to ksa.ae@astrazeneca.com

Date of Preparation: February 2022 Date of Expiry: February 2024
Approval Code: Z5-4977

AstraZeneca

For Gulf:
AstraZeneca FZ LLC Gulf; P.O. Box: 505070 Dubai, UAE; Dubai Healthcare City, Building 27, Block D 2nd Floor; Tel: +971(4)362 4888, Fax: +971(4)362 4898/9

For Saudi:
Al-Nakhla Tower - Floor 13th Ath Thumamah, Road - Al Sahafa
District. 7198 Unit No. 20 Riyadh 13315 – 3642.
Tel: +966 (011) 22 492 00; Fax: +966 (011) 22 492 91

SYNAGIS®
PALIVIZUMAB