

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

SYNAGIS® palivizumab injection

Read this carefully before your child starts taking **SYNAGIS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your child's healthcare professional about your child's medical condition and treatment and ask if there is any new information about **SYNAGIS**.

Serious Warnings and Precautions

- If your child has any of the signs or symptoms of a severe allergic reaction, call your healthcare provider and get medical help immediately.

What is SYNAGIS used for?

- The prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease.

SYNAGIS is not used to treat the symptoms of RSV disease once a child already has it. It is only used to prevent RSV disease.

SYNAGIS is not for adults or for children older than 24 months of age at the start of dosing.

How does SYNAGIS work?

SYNAGIS contains man-made, disease-fighting proteins called antibodies. These antibodies help prevent RSV disease. Children at high risk for severe RSV disease often do not have enough of their own antibodies. SYNAGIS is used in certain groups of children to help prevent severe RSV disease by increasing protective RSV antibodies.

What are the ingredients in SYNAGIS?

Medicinal ingredients: palivizumab

Non-medicinal ingredients: chloride, glycine, histidine and water

SYNAGIS comes in the following dosage forms:

SYNAGIS is available as a solution for injection, in a single-use vial containing either:

- 0.5 mL of solution for injection with a concentration of 100 mg/mL.
- 1 mL of solution for injection with a concentration of 100 mg/mL.

Do not use SYNAGIS if:

SYNAGIS is contraindicated in patients with known hypersensitivity to palivizumab injection or to any of its ingredients. It is also contraindicated in patients with known hypersensitivity to other humanized monoclonal antibodies.

Signs and symptoms of a severe allergic reaction can include:

- Severe rash, hives, or itching skin
- Swelling of the lips, tongue, or face
- Closing of the throat, difficult swallowing

- Difficult, rapid, or irregular breathing
- Bluish colour of skin, lips, or under fingernails
- Muscle weakness or floppiness
- A drop in blood pressure
- Unresponsiveness

To help avoid side effects and ensure proper use, talk to your child's healthcare professional before your child takes SYNAGIS. Talk about any health conditions or problems your child may have, including if your child:

- is unwell, as the use of SYNAGIS may need to be delayed.
- has any bleeding disorder, as SYNAGIS is usually injected into the thigh.

Tell your child's healthcare professional about all the medicines your child takes, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with SYNAGIS:

- The monoclonal antibody is specific for RSV. SYNAGIS is not expected to interfere with the immune response to vaccines, including live viral vaccines.

You should inform your child's doctor of all medicines your child is currently taking, especially blood thinner medicine, before starting SYNAGIS.

How to take SYNAGIS:

Usual dose:

The recommended dose of SYNAGIS is 15 mg/kg of body weight, **INTRAMUSCULAR INJECTION ONLY**, given once a month during anticipated periods of RSV risk in the community.

Overdose:

From the post-marketing experience, overdoses with doses up to 85 mg/kg have been reported and in some cases, adverse reactions were reported which did not differ from those observed with 15 mg/kg dose.

If you think your child has taken too much SYNAGIS, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If your child misses an injection, you should contact your child's doctor as soon as possible. Each injection of SYNAGIS can only help protect your child for about one month before another injection is needed.

What are possible side effects from using SYNAGIS?

These are not all the possible side effects your child may have when taking SYNAGIS. If your child experiences any side effects not listed here, tell your child's healthcare professional.

Like all medicines, SYNAGIS can cause side effects.

Some of the very common side effects that your child may have while on SYNAGIS include fever and rash. Some of the common side effects include nervousness, redness or swelling at the injection site. A pause in breathing or other breathing difficulties may also be common. Less common side effects include colds, coughs, runny nose, wheeze, vomiting, diarrhea, pain, viral infections and increase in liver function tests. Severe allergic reactions may occur after any dose of SYNAGIS. Such reactions may be life threatening or cause death. Severe allergic reactions may occur very rarely.

If a child shows **ANY** side effects after receiving SYNAGIS, you should contact your child's doctor. You should also notify your child's doctor of any side effects experienced that are not mentioned in this section.

Serious side effects and what to do about them			
Symptom / effect	Talk to your child's healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Fever		✓	
Rash		✓	
COMMON			
Nervousness		✓	
Redness or swelling at the injection site		✓	
A pause in breathing or any other breathing difficulties		✓	
RARE			
Colds		✓	
Coughs		✓	
Runny nose		✓	
Wheeze		✓	
Vomiting		✓	
Diarrhea		✓	
Pain		✓	
Viral infection		✓	
Increase in liver function tests		✓	
VERY RARE			
Severe allergic reaction		✓	

If your child has a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with his daily activities, tell your child's healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your child's health professional if you need information about how to manage your child's side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Upon receipt, SYNAGIS should be stored between 2 and 8°C in its original container. Do not freeze. Do not use beyond the expiration date.

The single-use vial of SYNAGIS solution for injection does not contain a preservative and should be administered immediately after drawing the dose into the syringe.

Keep out of reach and sight of children.

If you want more information about SYNAGIS:

- Talk to your child's healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.astrazeneca.ca, or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to date version can be found at www.astrazeneca.ca.

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