PART III: CONSUMER INFORMATION

[Pr]SYNAGIS® (Solution for Injection)
palivizumab

This leaflet is PART III of a three-part Product Monograph published when SYNAGIS was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about SYNAGIS. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is 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.

What it does:

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.

When it should not be used:

SYNAGIS is contraindicated in patients with known hypersensitivity to palivizumab 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

What the medicinal ingredient is:

palivizumab

What the important non-medicinal ingredients are:

SYNAGIS solution for injection also contains chloride, glycine, histidine and water.

What dosage forms it comes in:

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.

WARNINGS AND PRECAUTIONS

BEFORE you use SYNAGIS, talk to your doctor or pharmacist if:

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

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with SYNAGIS include:

- 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 doctor of all medicines your child is currently taking, especially blood thinner medicine, before starting SYNAGIS.

PROPER USE OF THIS MEDICATION

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 received too much SYNAGIS, contact your 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 doctor as soon as possible. Each injection of SYNAGIS can only help protect your child for about one month before another injection is needed.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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 doctor. You should also notify your doctor of any side effects experienced that are not mentioned in this section.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		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		√	
Uncommon	Colds		√	
	Coughs		√	
	Runny nose		√	
	Wheeze		√	
	Vomiting		√	
	Diarrhea		√	
	Pain		√	
	Viral infection		√	
	Increase in liver function tests		√	
Very rare	Severe allergic reaction		√	

This is not a complete list of side effects. For any unexpected effects while taking SYNAGIS, contact your doctor or pharmacist.

HOW TO STORE IT

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.

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 (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting) for information on how to report online, by mail or by fax; or

- Calling toll-free at 1-866-234-2345.

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

MORE INFORMATION

The most recent version of this document plus the full Product Monograph, prepared for health professionals, can be found at:

www.abbvie.ca

or by contacting the sponsor, AbbVie Corporation, Saint-Laurent, QC H4S 1Z1 at: 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

Last revised: April 09, 2018