

PART III: CONSUMER INFORMATION

PrSYNAGIS[®] 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.

What it does:

SYNAGIS[®] exhibits neutralizing activity against RSV. These activities inhibit RSV replication in laboratory experiments.

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.

What the medicinal ingredient is:

palivizumab

What the important non-medicinal ingredients are:

SYNAGIS[®] also contains glycine, histidine, and mannitol.

For a full listing of non-medicinal ingredients see PART I of the Product Monograph.

What dosage forms it comes in:

50 mg of lyophilized powder. Once reconstituted, the vial contains a solution of 50 mg / 0.5 mL.

100 mg of lyophilized powder. Once reconstituted, the vial contains a solution 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.

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 as high as 60 mg/kg have been reported without any untoward medical events.

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 common side effects that your child may have while on SYNAGIS[®] include fever, nervousness, redness or swelling at the injection site. Less common side effects include colds, coughs, runny nose, wheeze, vomiting, rash, diarrhea, pain, viral infections and increase in liver function tests. A pause in breathing or other breathing difficulties may occur rarely and severe allergic reactions 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	
Common	Fever		√	
	Nervousness		√	
	Redness or swelling at the injection site		√	
Uncommon	Colds		√	
	Coughs		√	
	Runny nose		√	
	Wheeze		√	
	Vomiting		√	
	Rash		√	
	Diarrhea		√	
	Pain		√	
	Viral infection increase in liver function tests		√	
Rare	A pause in breathing or any other breathing difficulties		√	
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 and until reconstitution for use, SYNAGIS® should be stored between 2 and 8°C in its original container. Do not freeze. Do not use beyond the expiration date.

Reconstituted product is stable for up to 6 hours when left at room temperature. **However, since the single-dose vial of SYNAGIS® does not contain a preservative, unless it is reconstituted under controlled and validated aseptic conditions, the product should be administered as soon as possible, preferably within 3 hours of reconstitution.**

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report on line at:
www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <http://www.healthcanada.gc.ca/medeffect>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at:

<http://www.abbott.ca>
or by contacting the sponsor, Abbott Laboratories, Limited, Saint-Laurent, Qc H4S 1Z1 at:
1-800-699-9948

This leaflet was prepared by Abbott Laboratories, Limited.

Last revised: December 16, 2009.