

PART III: CONSUMER INFORMATION

^{Pr}ARGATROBAN (argatroban for injection)

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

ABOUT THIS MEDICATION

What the medication is used for:

ARGATROBAN is used to prevent blood clots from forming in patients who have received therapy with heparin (another type of blood thinner used to treat blood clots) and developed blood clots as a result of the heparin therapy.

What it does:

ARGATROBAN reduces or stops the activity of thrombin, a component in the blood which is necessary for blood clotting.

When it should not be used:

Do not take ARGATROBAN if you:

- are hypersensitive or "allergic" to the active ingredient argatroban or to any ingredient in the formulation (see 'What the nonmedicinal ingredients are:' section)
- have active major bleeding or a bleeding disorder
- have a rare disease known as hereditary fructose intolerance

The safety of ARGATROBAN has not been established in children age 18 and younger.

What the medicinal ingredient is:

argatroban.

What the nonmedicinal ingredients are:

D-sorbitol, dehydrated alcohol and water for injection.

What dosage forms it comes in:

Liquid for intravenous injection; 250 mg/2.5 ml vial.

WARNINGS AND PRECAUTIONS

BEFORE you use ARGATROBAN talk to your doctor or pharmacist if:

- you have or have had a bleeding disorder, such as hemophilia (a condition where blood takes a long time to clot) or ulcers (a condition in which sores and possibly bleeding occur in the stomach or intestines);
- you have high blood pressure;
- you have had or about to have surgery;
- you are pregnant or nursing;
- you have a liver disease.

INTERACTIONS WITH THIS MEDICATION

Before taking ARGATROBAN, tell your doctor, nurse or pharmacist about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines, and:

- Medications used to prevent blood clotting such as ASA, clopidogrel, ticlopidine, prasugrel, ticagrelor
- Medications used to thin the blood such as warfarin, heparin, low molecular weight heparins
- Acetaminophen (a drug taken for pain)

PROPER USE OF THIS MEDICATION

ARGATROBAN must be administered by a physician experienced in anti-thrombotic therapy.

ARGATROBAN is supplied as a concentrate. It should be properly diluted prior to administration. It should not be mixed with other drugs prior to dilution in an infusion. Dosage details can be found in the product monograph.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its intended action, any medication, including ARGATROBAN, may cause side effects. Most adverse events are mild and tend to diminish with continuation of therapy.

The most common side effects are bleeding, stomach upset (nausea and vomiting), diarrhea, low blood pressure, difficulty breathing, increased heart beat, dizziness, fever and chest pain.

The most serious side effect is unusual bleeding (such as hemorrhage) (see **When it should not be used and WARNINGS AND PRECAUTIONS**).

The following table contains a list of side effects that may occur with ARGATROBAN. The table does not contain a complete list. **Therefore, discuss any unusual symptoms you experience with your doctor right away.**

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 seek immediate medical help
		Only if severe	In all cases	
Any observed side effect with this drug including:	Any unusual bleeding		√	
	Stomach pain, nausea or diarrhea		√	
	Difficulty Breathing		√	
	Chest pain		√	
	Dizziness		√	
	Fever		√	
	Rapid heartbeat		√	
	Pain		√	
	Infection		√	
Unknown	Allergic reaction (symptoms like itching, swelling of the face, lips tongue and throat, difficulty breathing)			√

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

HOW TO STORE IT

Store the vials in the original cartons at room temperature (15 – 25°C, 59 – 77°F). Do not freeze. Store in carton until use.

PROTECT FROM LIGHT.

Discard prepared solution if haziness, particulate matter, precipitate, discoloration or leakage is found upon inspection.

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 online 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, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at 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: www.novartis.ca or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at 1-800-363-8883

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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