

**PART III: CONSUMER INFORMATION**

Pr **Persantine®**  
**Dipyridamole for injection**

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

**ABOUT THIS MEDICATION****What the medication is used for:**

PERSANTINE ampoules for intravenous injection are used in a medical test (cardiac perfusion imaging) together with a radioactive substance to assess the flow of blood to the heart muscle. The test will help your doctor determine if there are areas of your heart which do not receive enough blood supply due to coronary artery disease.

Generally, cardiac perfusion imaging is done after an exercise/treadmill stress test. For patients who are unable to exercise adequately, the test is done after injection of PERSANTINE that mimics the effect of exercise on the heart.

**What it does:**

PERSANTINE dilates the blood vessels of the heart muscle and increases the blood flow to your heart.

**When it should not be used:**

PERSANTINE should not be used by patients with allergic reactions to dipyridamole or any component of the drug.

**What the medicinal ingredient is:**

Dipyridamole

**What the non-medicinal ingredients are:**

Tartaric acid, polyethylene glycol, hydrochloric acid and sterile water for injection.

**What dosage forms it comes in:**

PERSANTINE comes in 10 mL ampoules, containing 50 mg of dipyridamole.

**WARNINGS AND PRECAUTIONS**

Since this drug may cause sudden death, cardiac arrest and ECG change, it should be only used in a clinical setting with appropriate equipment and under the monitoring of trained health professionals.

**BEFORE you use PERSANTINE talk to your doctor or pharmacist if:**

- You are allergic to dipyridamole or any other ingredient in the drug.
- You have or ever had any heart problems, such as a recent heart attack (within the last 4 weeks), coronary artery disease, angina (chest pain) at rest, irregular heart beat,

heart block (this usually causes a slow heart beat), heart failure or a problem affecting the heart valves.

- You have low blood pressure.
- You had a stroke or something called a transient ischemic attack (temporary stroke symptoms lasting less than 24 hours).
- You have breathing problems such as asthma, shortness of breath or wheezing.
- You have myasthenia gravis (a rare muscle problem).
- You are pregnant, likely to become pregnant, or are breast-feeding.

During the test, reactions similar to exercise-induced stress may occur; therefore your doctor will monitor you. Patients with a history of severe coronary heart disease or history of asthma may be at a greater risk. Abnormal heart beat, chest pain, bronchospasm or severe drop in blood pressure can occur. Your doctor may use another medication (aminophylline and nitroglycerin) to reverse these symptoms.

**INTERACTIONS WITH THIS MEDICATION**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines.

Drugs that may interact with PERSANTINE include: adenosine, other drugs that prevent blood clotting, blood pressure lowering drugs, and cholinesterase inhibitors.

Tell your doctor about all medication that you are currently taking. Some medication may have to be stopped temporarily 24 hours before the test.

Theophylline or caffeine-containing drugs or food products and beverages (soft drinks, coffee, tea and chocolates) containing caffeine should be stopped 24 hours before the stress test.

**PROPER USE OF THIS MEDICATION****Usual dose:**

PERSANTINE ampoules are usually given as an injection by a doctor or nurse.

Another injection containing the imaging agent is given within 5 minutes of the PERSANTINE injection.

**Overdose:**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

No cases of overdose have been reported in this indication. In case of overdose you may feel warm, flushes, sweating, accelerated pulse, restlessness, feeling of weakness and dizziness, and may have chest pain or difficulty breathing. A drop in blood pressure and fast heart rate might be observed. Your doctor may use another medication (aminophylline) to reverse these symptoms.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, PERSANTINE can cause side effects although not everybody gets them.

The following side effects have been observed during cardiac perfusion imaging with PERSANTINE. If you experience any of the following side effects, tell your doctor immediately:

Frequency	Symptom/effect
Very common	Headache
	Dizziness
	Chest pain/angina pectoris
Common	Tingling, prickling sensation
	Irregular heartbeat
	Rapid heartbeat
	Drop in blood pressure (feeling lightheaded, dizzy or faint)
	Hot flush (feeling intensive warmth with sweating and rapid heartbeats)
	Nausea
Uncommon	Heart attack
	Slow heartbeat
	Difficulty breathing, wheezing
	Abdominal pain
Rare	Excessive allergic reaction (symptoms could be itchy rash, swelling of lips, tongue and /or throat, runny nose, light headedness, headache, shortness of breath, hoarseness, cough and low blood pressure)
	Temporary symptoms of stroke
Very rare	Stroke
	Seizure
	Uncoordinated contraction of the cardiac muscle of the ventricles in the heart
Not known*	Swelling of the skin and the mucosa of the mouth and/or throat and tongue
	Fainting
	Temporary pause in the normal heart rhythm
	Impairment of the conduction between the atria and ventricles of the heart.
	Spasmodic closure of the voice box
	Diarrhea
	Vomiting
	Hives

Frequency	Symptom/effect
	Rash
	Muscle pain

\*A precise estimation of frequency is not possible as the adverse drug reactions did not occur in a clinical trial.

If you experience dizziness during the test, you should avoid potentially dangerous tasks such as driving or operating machines 24 hours after the test.

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

**HOW TO STORE IT**

Protect PERSANTINE ampoules from direct light, and avoid freezing.

**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](http://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](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.boehringer-ingelheim.ca> or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 84633 (Medical Information).

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd.

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