

## PART III: CONSUMER INFORMATION

### NITROSTAT® (nitroglycerin sublingual tablets USP)

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

#### ABOUT THIS MEDICATION

##### What the medication is used for:

NITROSTAT is used for acute relief of a type of chest pain called angina. Angina is a pain or discomfort that keeps coming back when part of your heart does not get enough blood. Angina feels like a pressing or squeezing pain, usually in your chest under the breastbone. Sometimes you can feel it in your shoulders, arms, neck, jaws, or back. NITROSTAT can relieve this pain.

##### What it does:

NITROSTAT works by relaxing blood vessels and increasing the supply of blood and oxygen to the heart.

##### When it should not be used:

Do not use NITROSTAT if you are allergic to organic nitrates (such as the active ingredient in NITROSTAT) or any of its non-medicinal ingredients.

You should not take NITROSTAT if you have the following conditions:

- very recent heart attack
- severe anemia (low number of red blood cells)
- increased pressure in the head

Do not take NITROSTAT with drugs for erectile dysfunction, like Viagra (sildenafil citrate), Cialis (tadalafil), or Levitra (vardenafil) as this may lead to extreme lowering of your blood pressure.

Do not take NITROSTAT with drugs for pulmonary hypertension, like Adempas (riociguat), as this may lead to lowering of your blood pressure.

##### What the medicinal ingredient is:

Nitroglycerin

##### What the nonmedicinal ingredients are:

calcium stearate, glyceryl monostearate, lactose monohydrate, pregelatinized starch, silicon dioxide.

##### What dosage forms it comes in:

sublingual tablets, 0.3 mg and 0.6 mg.

#### WARNINGS AND PRECAUTIONS

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

- have hypotension (low blood pressure).
- are pregnant, think you may be pregnant, or are planning to become pregnant.
- are breast-feeding.

#### INTERACTIONS WITH THIS MEDICATION

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food store without a prescription.

Before using NITROSTAT, tell your doctor if you are taking:

- medicines that are used to treat angina, heart failure, or an irregular heartbeat.
- medicines that reduce blood pressure.
- diuretics (water pills).
- medicines to treat depression or psychiatric illness.
- ergotamine or similar drugs for migraine headaches.

- aspirin.
- blood thinner medicine heparin.
- medicines for erectile dysfunction.
- medicines for pulmonary hypertension

### PROPER USE OF THIS MEDICATION

Usual adult dose: Dissolve one tablet underneath the tongue (sublingual use) or in the mouth at the first sign of chest pain.

- You should sit down when taking NITROSTAT tablets and be careful when you stand up. This eliminates the possibility of falling due to light headedness or dizziness.
- The dose may be repeated approximately every 5 minutes, until the chest pain is relieved.
- If the pain persists after a total of 3 tablets in a 15-minute period, or is different than you typically experience, seek emergency medical help.
- NITROSTAT may be used 5 to 10 minutes prior to activities that might cause chest pain.
- You may feel a burning or tingling sensation in your mouth when you take NITROSTAT.
- Always take the tablets exactly as your doctor tells you to. Do not change the dose or stop taking NITROSTAT without talking to your doctor.
- Do not chew, crush, or swallow NITROSTAT tablets.
- Do not consume alcohol while taking NITROSTAT as this can lower your blood pressure.

### 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.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, NITROSTAT can cause some side effects. For most patients, these side effects are likely to be minor and temporary. However, some may be serious. Consult your doctor or pharmacist as soon as you can, if you do not feel well while taking NITROSTAT.

NITROSTAT may cause the following side effects: low blood pressure upon rising from a seated position, sweating, paleness, other skin reactions that may be severe.

NITROSTAT may cause a false test result of decreased serum cholesterol.

NITROSTAT may cause dizziness, vertigo, or fainting. Avoid driving or operating machinery until you are sure that NITROSTAT does not affect your ability to perform these activities.

**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	
	Allergic reaction involving swelling of the face, lips and/or tongue accompanied by difficulty breathing			✓
	Dizziness, vertigo (a major symptom of balance disorder)	✓		
	Weakness	✓		
	Nausea, vomiting	✓		
	Flushing (warm or red condition of your skin)	✓		
	Syncope: Fainting or unusually rapid heart beat		✓	
	Hypotension: low blood pressure upon rising from a seated position		✓	
	Headache	✓		
	Skin reactions: rash, blistering, or peeling of the skin		✓	

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

**HOW TO STORE IT**

NITROSTAT should be kept in the original glass container and tightly capped after each use. Store NITROSTAT tablets at room temperature between 15-30° C. Keep out of the sight and reach of children.

**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, 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 [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.viatris.ca> or by contacting the sponsor, BGP Pharma ULC, at: 1-844-596-9526

This leaflet was prepared by BGP Pharma ULC.

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