

PART III: CONSUMER INFORMATION

RHO-NITRO[®] PUMPSPRAY
(Nitroglycerin Sublingual Spray)

This leaflet is part III of a three-part "Product Monograph" published for RHO-NITRO[®] PUMPSPRAY and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about RHO-NITRO[®] PUMPSPRAY. Contact your doctor, nurse or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

RHO-NITRO[®] PUMPSPRAY is used in adults for the treatment of acute attacks of angina pectoris – chest pain which occurs when the heart muscle does not get as much blood (hence as much oxygen) as it needs.

What it does:

RHO-NITRO[®] PUMPSPRAY belongs to a group of drugs, which reduce the oxygen demand of the heart.

When it should not be used:

Do not use RHO-NITRO[®] PUMPSPRAY if you:

- Are allergic to nitroglycerin or any of the non-medicinal ingredients in the formulation or to any other medication of the same group of medicines called nitrates
- Have an eye disease called closed angle glaucoma
- Are having a heart attack (myocardial infarction)
- Have low iron levels in your blood or low red blood cell count (severe anemia)
- Have low blood pressure (hypotension) or a diagnosis of heart failure
- Have a condition caused by an increase in normal brain pressure (increased intracranial pressure)
- Are taking tadalafil, vardenafil, sildenafil citrate or any similar medication for impotence (erectile dysfunction).
- Are taking riociguat for high blood pressure in your lungs (chronic thromboembolic pulmonary hypertension (CTEPH) or pulmonary arterial hypertension (PAH))
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What the medicinal ingredient is:

Nitroglycerin

What the important nonmedicinal ingredients are:

Ethanol anhydrous, medium chain partial glycerides, medium chain triglycerides, and peppermint oil.

What dosage forms it comes in:

Spray bottles delivering 200 metered doses of 0.4 mg nitroglycerin per spray emission

Serious Warnings and Precautions

Headaches or symptoms of low blood pressure, such as weakness or dizziness, especially when you go from lying/sitting to standing up, may be due to taking too much RHO-NITRO[®] PUMPSPRAY. You may also notice a bluish discoloration to your skin, especially around your lips and mouth. If these symptoms occur, talk to your doctor, nurse or pharmacists as your dose of RHO-NITRO[®] PUMPSPRAY may need to be reduced..

BEFORE you use RHO-NITRO[®] PUMPSPRAY talk to your doctor, nurse or pharmacist if:

- You are currently taking any other medications, whether on prescription or otherwise (see Interactions with this Medication section below)
- You have headaches, weakness or dizziness especially when getting up suddenly from a laying down or sitting position, or symptoms of low blood pressure (hypotension)
- You are breast feeding, pregnant, or think you might be pregnant
- You had a heart attack
- Are less than 18 years old

Tolerance to RHO-NITRO[®] PUMPSPRAY and similar drugs can occur after long periods of use. Chronic use can lead to angina attacks being brought on more easily. Do not suddenly stop using RHO-NITRO[®] PUMPSPRAY. Talk to your doctor if you wish to discontinue using RHO-NITRO[®] PUMPSPRAY.

RHO-NITRO[®] PUMPSPRAY is not for use in children.

Driving and using machines: Temporary dizziness may be associated with the use of RHO-NITRO[®] PUMPSPRAY. Make sure you know how you react to this medicine before you drive, operate machinery, or do anything requiring you to be alert.

Avoid alcoholic beverages until you have discussed their use with your doctor.

The spray should be kept away from the eyes and it should not be inhaled.

INTERACTIONS WITH THIS MEDICATION

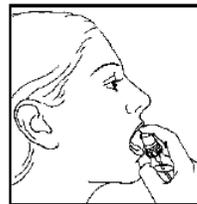
As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

WARNINGS AND PRECAUTIONS

Serious Drug Interactions

If you are currently taking medications for the treatment of impotence (erectile dysfunction), such as sildenafil citrate, tadalafil or vardenafil or any other similar medication (PDE5 inhibitors), the use of RHO-NITRO[®] PUMPSPRAY may lead to extreme low blood pressure resulting in fainting, heart attack and death.

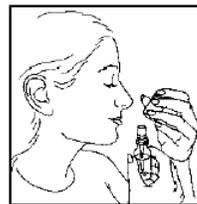
If you are being treated with any of these drugs and need RHO-NITRO[®] PUMPSPRAY (e.g. in case of chest pain caused by an acute attack of angina pectoris) please seek emergency medical assistance immediately.



4. Open your mouth and bring the container as close to it as possible.
5. Press the button firmly with the forefinger to release the spray onto or under the tongue.

DO NOT INHALE THE SPRAY.

KEEP THE SPRAY AWAY FROM EYES



6. Release button and close mouth.
7. If you require a second dose, repeat steps 4, 5 and 6.
8. Replace the plastic cover.

The following may interact with RHO-NITRO[®] PUMPSPRAY:

- Medications used to treat hypertension (high blood pressure) such as:
 - Diuretics (“water pills”)
 - Calcium Channel Blockers [medications used to treat conditions such as high blood pressure, angina (chest pain), and other heart conditions (e.g. diltiazem, nifedipine, verapamil)]
- Tricyclic antidepressants (e.g.: imipramine, amitriptyline, desipramine, nortriptyline)
- Antipsychotics (medications used to treat schizophrenia or bipolar depression)
- Medications used to relieve muscle spasms including tizanidine
- Alcoholic beverages (when combined with RHO-NITRO[®] PUMPSPRAY it may cause your blood pressure to drop too low)
- Topical anesthetics pilocaine/lidocaine

When using this product for the first time, familiarize yourself with how to use it by testing the spray into the air (away from yourself and others). Get the feel of the finger resting on the groove button so that you can use the spray in the dark.

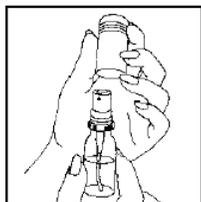
Usual adult dose:

RHO-NITRO[®] PUMPSPRAY should be taken as prescribed by your doctor.

During an anginal attack, one or two doses should be sprayed onto or under the tongue, **without inhaling**. Your doctor can help you to discover the exact dose which will be best for you. Administer at rest, ideally in the sitting position. A dose may be repeated twice at 5-10 minute intervals. If the pain persists, seek emergency medical assistance.

PROPER USE OF THIS MEDICATION

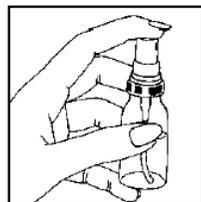
Ideally, you should sit and rest while taking this medication.



1. Holding container in upright position, remove the plastic cover.

DO NOT SHAKE.

2. The container must be primed prior to the first use. To prime, point away from face, press the button firmly with the forefinger to release one spray. Repeat this 3 times. Now your container is primed and ready for use.



Repriming is only necessary when the container has not been used for more than 14 days. To reprime, release 1 spray as directed previously. There is no need to reprime the container between more frequent usage.

3. Hold the container upright with forefinger on top of the grooved button. There is no need to shake the container.

MAKE SURE THAT YOU HAVE A SPARE PUMPSPRAY READILY AVAILABLE (TO PREVENT RUNNING OUT WHEN NEEDED).

Overdose:

Symptoms of overdosage may include: flushing, headache, nausea, dizziness, and hypotension.

If you think you have taken too much RHO-NITRO[®] PUMPSPRAY contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison control Centre immediately, even if there are no symptoms..

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its intended action, any medication, including RHO-NITRO[®] PUMPSPRAY, may cause side effects. After you have started taking RHO-NITRO[®] PUMPSPRAY, it is important that you tell your doctor at once about any unexplained symptom you might experience.

Side effects may include:

- Headache,
- Sore throat and/or mouth, runny nose
- Restlessness

If any of these affects you severely, tell your doctor, nurse or pharmacist.

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

| Symptom / effect | | Talk with your doctor, nurse or pharmacist | | Stop taking drug and seek immediate emergency medical attention |
|---|---|--|--------------|---|
| | | Only if severe | In all cases | |
| Allergic reaction involving skin rash or swelling of the face, lips and/or tongue accompanied by difficulty breathing | | | | ✓ |
| Common | Severe, persistent headache | | ✓ | |
| | Dizziness | | ✓ | |
| | Weakness | | ✓ | |
| | Abdominal pain | | ✓ | |
| | Swelling of the ankles | | ✓ | |
| | Tingling or pins and needles of a limb | | ✓ | |
| | Shortness of breath | | ✓ | |
| Uncommon | Nausea | | ✓ | |
| | Sweating | ✓ | | |
| | Rash | ✓ | | |
| | Flushing | | ✓ | |
| | Chest pain | | ✓ | |
| | Racing heart rate and/or palpitations (irregular heartbeat) | | ✓ | |
| | Pallor | | ✓ | |
| | Vomiting | | | ✓ |
| | Low blood pressure (hypotension). This can be severe, leading to slow or fast heartbeat, fainting or dizziness when you change from lying/sitting to standing up. | | | ✓ |
| | Fainting | | | ✓ |

This is not a complete list of side effects. For any unexpected effects while taking RHO-NITRO® PUMPSPRAY, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

Contains alcohol. Do not open container forcefully or burn after use. Do not spray toward flames. Do not place RHO-NITRO® PUMPSPRAY in hot water or near radiators, stoves or other sources of heat. Do not expose to temperature over 40°C. Store at room temperature (15°C to 30°C).

Keep in a safe place and out of the reach and sight 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
- ☒ 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 obtained by contacting the sponsor, Sandoz Canada Inc., at:

1-800-361-3062

or by written request at:
145, Jules-Léger
Boucherville, (QC), Canada
J4B 7K8

or by email at :
medinfo@sandoz.com

This leaflet was prepared by Sandoz Canada Inc.

Last revised: September 25, 2015