

NITROMIST- nitroglycerin aerosol, spray
NovaDel Pharma Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

----- **INDICATIONS AND USAGE** -----

NitroMist™ is a nitrate vasodilator indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease (1).

----- **DOSAGE AND ADMINISTRATION** -----

- At the onset of an attack, one or two metered sprays should be administered on or under the tongue. A spray may be repeated approximately every 5 minutes as needed (2.1).
- Maximum of 3 metered sprays are recommended within a 15-minute period. If chest pain persists after a total of 3 sprays, prompt medical attention is recommended (2.1).
- May be used prophylactically 5 to 10 minutes before engaging in activities that might precipitate an acute attack (2.1).

----- **DOSAGE FORMS AND STRENGTHS** -----

Lingual aerosol, 400 mcg per spray, 230 metered sprays per container (3)

----- **CONTRAINDICATIONS** -----

- Use of a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5 inhibitors), such as sildenafil, vardenafil, and tadalafil (4.1)
- Severe anemia (4.2)
- Increased intracranial pressure (4.3)
- History of hypersensitivity to NitroMist or to other nitrates or nitrites (4.4)

----- **WARNINGS AND PRECAUTIONS** -----

- Tolerance: Excessive use may lead to tolerance (5.1).

----- **ADVERSE REACTIONS** -----

Most common adverse reactions are headache, flushing, hypotension, and syncope (6).

----- **DRUG INTERACTIONS** -----

- PDE5 inhibitors: Concomitant use contraindicated (4.1, 7.1)
- Antihypertensives: Possible additive hypotensive effects (7.2)
- Aspirin: increased nitroglycerin levels (7.3)
- Tissue-type plasminogen activator (t-PA): decreased thrombolytic effect (7.4)
- Heparin: anticoagulant effect of heparin may be reduced. Monitor APTT. (7.5)
- Ergotamine: increased bioavailability of ergotamine. Avoid concomitant use. (7.6)

See 17 for PATIENT COUNSELING INFORMATION.

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

NitroMist is indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

At the onset of an attack, one or two metered sprays should be administered on or under the tongue. A spray may be repeated approximately every 5 minutes as needed. No more than 3 metered sprays are recommended within a 15-minute period. If chest pain persists after a total of 3 sprays, prompt medical attention is recommended. NitroMist may be used prophylactically 5 to 10 minutes before engaging in activities that might precipitate an acute attack.

2.2 Priming the Container

After an initial priming of 10 sprays, each metered spray of NitroMist delivers 33 mg of solution containing 400 mcg of nitroglycerin. It will remain adequately primed for 6 weeks. If the product is not used within 6 weeks, it can be adequately re-primed with 2 sprays. There are 230 metered sprays per container, but the total number of available doses depends on the number of sprays per use (1 or 2 sprays), and the frequency of priming.

2.3 Administration

During use the patient should rest, ideally in the sitting position. The container should be held vertically with the valve head uppermost and the spray orifice as close to the mouth as possible. The dose should preferably be sprayed into the mouth on or under the tongue by pressing the button firmly and the mouth should be closed immediately after each dose. **THE SPRAY SHOULD NOT BE INHALED.** Patients should be instructed to familiarize themselves with the position of the spray orifice, which can be identified by the finger rest on top of the valve, in order to facilitate orientation for administration at night.

1. Do not shake container.
2. Remove plastic cap
3. Press actuator button 10 times to ensure proper dose priming (holding unit away from yourself and others).
4. Hold container upright with forefinger on top of the actuator button.
5. Open mouth and bring the container as close as possible.
6. Press the actuator button firmly with forefinger to release spray onto or under the tongue.
7. Release button and close mouth. The medication should not be spit out or the mouth rinsed for 5 to 10 minutes following administration.
8. If a second administration is required to obtain relief, repeat steps 4, 5, and 6.
9. Replace plastic cover.
10. If the product is not used for more than 6 weeks, then it can be adequately re-primed with 2 sprays.

The level of the liquid in the container should be periodically checked. While the container is in the upright position, if the liquid reaches the top or middle of the hole on the side of the container, one should order more. When the liquid reaches the bottom of the hole, the remaining doses will have less than label content.

3 DOSAGE FORMS AND STRENGTHS

Lingual aerosol, 400 mcg per spray, 230 metered sprays per container

4 CONTRAINDICATIONS

4.1 PDE5 inhibitor use

Administration of NitroMist is contraindicated in patients who are using a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5), as PDE5 inhibitors such as sildenafil, vardenafil, and tadalafil have been shown to potentiate the hypotensive effects of organic nitrates [see **DRUG INTERACTIONS 7.1**].

4.2 Severe anemia

NitroMist is contraindicated in patients with severe anemia.

4.3 Increased intracranial pressure

NitroMist is contraindicated in patients with increased intracranial pressure

4.4 Hypersensitivity

NitroMist is contraindicated in patients who have shown hypersensitivity to it or to other nitrates or nitrites. Skin reactions consistent with hypersensitivity have been observed with organic nitrates.

5 WARNINGS AND PRECAUTIONS

5.1 Tolerance

Excessive use may lead to the development of tolerance. Only the smallest number of doses required for effective relief of the acute anginal attack should be used [see ***DOSAGE AND ADMINISTRATION (2)***].

As tolerance to other forms of nitroglycerin develops, the effect of sublingual nitroglycerin on exercise tolerance, although still observable, is reduced.

5.2 Hypotension

Severe hypotension, particularly with upright posture, may occur even with small doses of nitroglycerin. The drug should therefore be used with caution in patients who may be volume-depleted or who, for whatever reason, are already hypotensive. Hypotension induced by nitroglycerin may be accompanied by paradoxical bradycardia and increased angina pectoris.

The benefits of NitroMist in patients with acute myocardial infarction or congestive heart failure have not been established. If one elects to use NitroMist in these conditions, careful clinical or hemodynamic monitoring must be used because of the possibility of hypotension and tachycardia.

5.3 Hypertrophic Cardiomyopathy

Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy.

5.4 Headache

Nitroglycerin produces dose-related headaches, which may be severe. Tolerance to headaches occurs.

6 ADVERSE REACTIONS

6.1 Headache

Headache, which may be severe and persistent, may occur immediately after nitroglycerin use.

6.2 Flushing

Flushing, drug rash and exfoliative dermatitis have been reported in patients receiving nitrate therapy.

6.3 Hypotension

Postural hypotension, as manifest by vertigo, weakness, palpitation, and other symptoms, may develop occasionally, particularly in erect, immobile patients. Marked sensitivity to the hypotensive effects of nitrates (manifested by nausea, vomiting, weakness, diaphoresis, pallor, and collapse) may occur at therapeutic doses.

6.4 Syncope

Syncope due to nitrate vasodilatation has been reported.

7 DRUG INTERACTIONS

7.1 PDE5 inhibitors

Administration of NitroMist is contraindicated in patients who are using a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5). PDE5 inhibitors such as sildenafil, vardenafil, and tadalafil have been shown to potentiate the hypotensive effects of organic nitrates.

The time course and dose dependence of this interaction have not been studied, and use within a few days of one another cannot be recommended. Appropriate supportive care for the severe hypotension has not been studied, but it seems reasonable to treat this as a nitrate overdose, with elevation of the extremities and with central volume expansion. The use of any form of nitroglycerin during the early days of acute myocardial infarction requires particular attention to hemodynamic monitoring and clinical status.

7.2 Antihypertensives

Patients receiving antihypertensive drugs, beta-adrenergic blockers, and nitrates should be observed for possible additive hypotensive effects. Marked orthostatic hypotension has been reported when calcium channel blockers and organic nitrates were used concomitantly.

Labetolol blunts the reflex tachycardia produced by nitroglycerin without preventing its hypotensive effects. If labetolol is used with nitroglycerin in patients with angina pectoris, additional hypotensive effects may occur.

7.3 Aspirin

Coadministration of aspirin and nitroglycerin has been reported to result in increased nitroglycerin maximum concentrations by as much as 67% and AUC by 73% when administered as a single dose. The vasodilatory and hemodynamic effects of nitroglycerin may be enhanced by concomitant administration of aspirin.

7.4 Tissue-type Plasminogen Activator (t-PA)

Intravenous administration of nitroglycerin decreases the thrombolytic effect of tissue-type plasminogen activator (t-PA). Plasma levels of t-PA are reduced when coadministered with nitroglycerin. Therefore, caution should be observed in patients receiving nitroglycerin during t-PA therapy.

7.5 Heparin

Intravenous nitroglycerin reduces the anticoagulant effect of heparin. Activated partial thromboplastin times (APTT) should be monitored in patients receiving heparin and intravenous nitroglycerin. It is not known if this effect occurs following single nitroglycerin doses.

7.6 Ergotamine

Oral administration of nitroglycerin markedly decreases the first-pass metabolism of dihydroergotamine and subsequently increases its oral bioavailability. Ergotamine is known to precipitate angina pectoris. Therefore, patients receiving sublingual nitroglycerin should avoid ergotamine and related drugs or be monitored for symptoms of ergotism if this is not possible.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy category C: Animal reproduction and teratogenicity studies have not been conducted with NitroMist or nitroglycerin sublingual tablets. It is also not known whether NitroMist can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. A teratogenicity study was conducted in the third mating of F₀ generation female rats administered dietary nitroglycerin for gestation days 6 to 15 at dose levels used in the 3-generation reproduction study. In offspring of the high-dose nitroglycerin group, increased incidence of diaphragmatic hernias and decreased hyoid bone ossification were seen. The latter finding probably reflects delayed development rather than a potential teratogenic effect, thus indicating no clear evidence of teratogenicity of nitroglycerin.

There are no adequate and well controlled studies in pregnant women. NitroMist should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

It is not known whether nitroglycerin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when NitroMist is administered to a nursing woman.

8.4 Pediatric Use

The safety and effectiveness of nitroglycerin in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of NitroMist did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly (≥ 65 years) and younger (< 65 years) patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

10 OVERDOSAGE

Signs and symptoms of hemodynamic effects: The effects of nitroglycerin overdose are generally the results of nitroglycerin's capacity to induce vasodilatation, venous pooling, reduced cardiac output, and hypotension. These hemodynamic changes may have protean manifestations, including increased intracranial pressure with any or all of persistent throbbing headache, confusion, and moderate fever; vertigo; palpitations; tachycardia; visual disturbances; nausea and vomiting (possibly with colic and even bloody diarrhea); syncope (especially in the upright posture); dyspnea, later followed by reduced ventilatory effort, diaphoresis, with the skin either flushed or cold and clammy; heart block and bradycardia; paralysis; coma; seizures; and death.

No specific antagonist to the vasodilator effects of nitroglycerin is known, and no intervention has been subject to controlled study as a therapy of nitroglycerin overdose. Because the hypotension associated with nitroglycerin overdose is the result of venodilatation and arterial hypovolemia, prudent therapy in this situation should be directed toward increase in central fluid volume. Passive elevation of the patient's legs may be sufficient, but intravenous infusion of normal saline or similar fluid may also be necessary.

The use of epinephrine or other arterial vasoconstrictors in this setting is not recommended.

In patients with renal disease or congestive heart failure, therapy resulting in central volume expansion is not without hazard. Treatment of nitroglycerin overdose in these patients may be subtle and difficult, and invasive monitoring may be required.

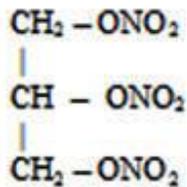
Methemoglobinemia: Methemoglobinemia has been rarely reported with organic nitrates. The diagnosis should be suspected in patients who exhibit signs of impaired oxygen delivery despite adequate arterial

PO₂. Classically, methemoglobinemic blood is described as chocolate brown, without color change on exposure to air.

If methemoglobinemia is present, intravenous administration of methylene blue, 1 to 2 mg/kg of body weight, may be required.

11 DESCRIPTION

Nitroglycerin, an organic nitrate, is a vasodilator which has effects on both arteries and veins. The chemical name for nitroglycerin is 1,2,3-propanetriol trinitrate (C₃H₅N₃O₉). The compound has a molecular weight of 227.09. The chemical structure is:



NitroMist (nitroglycerin) lingual aerosol is a metered-dose spray containing 230 metered sprays of nitroglycerin. This product delivers 400 mcg of nitroglycerin per actuation in the form of spray droplets on or under the tongue. Inactive ingredients: caprylic/capric diglycerol succinate, peppermint oil, L-menthol, n-butane.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Nitroglycerin forms free radical nitric oxide (NO), which activates guanylate cyclase, resulting in an increase of guanosine 3',5'-monophosphate (cyclic GMP) in smooth muscle and other tissues. This eventually leads to dephosphorylation of myosin light chains, which regulates the contractile state in smooth muscle and results in vasodilatation.

12.2 Pharmacodynamics

The principal pharmacological action of nitroglycerin is relaxation of vascular smooth muscle. Although venous effects predominate, nitroglycerin produces, in a dose-related manner, dilation of both arterial and venous beds. Dilation of the postcapillary vessels, including large veins, promotes peripheral pooling of blood, decreases venous return to the heart, and reduces left ventricular end-diastolic pressure (preload). Nitroglycerin also produces arteriolar relaxation, thereby reducing peripheral vascular resistance and arterial pressure (after load), and dilates large epicardial coronary arteries; however, the extent to which this latter effect contributes to the relief of exertional angina is unclear.

Therapeutic doses of nitroglycerin may reduce systolic, diastolic and mean arterial blood pressure. Effective coronary perfusion pressure is usually maintained, but can be compromised if blood pressure falls excessively or increased heart rate decreases diastolic filling time. Elevated central venous and pulmonary capillary wedge pressures, and pulmonary and systemic vascular resistance are also reduced by nitroglycerin therapy. Heart rate is usually slightly increased, presumably a reflex response to the fall in blood pressure. Cardiac index may be increased, decreased, or unchanged. Myocardial oxygen consumption or demand (as measured by the pressure-rate product, tension-time index, and stroke-work index) is decreased and a more favorable supply-demand ratio can be achieved. Patients with elevated left ventricular filling pressure and increased systemic vascular resistance in association with a depressed cardiac index are likely to experience an improvement in cardiac index. In contrast, when filling pressures and cardiac index are normal, cardiac index may be

slightly reduced following nitroglycerin administration.

12.3 Pharmacokinetics

Nitroglycerin is rapidly absorbed following lingual spray administration. In a pharmacokinetic study when a single 1200 mcg dose (three activations of a 400 mcg dose) of NitroMist was administered to healthy volunteers (n=12), all subjects had detectable trinitroglycerin plasma levels (mean C_{max} 0.8 ± 0.7 ng/mL and t_{max} of 8 minutes, range 4 to 15 minutes) beginning at 2 minutes post-dose and higher levels of the 1,2- (mean C_{max} 3.7 ± 1 ng/mL and t_{max} 34 ± 21 minutes, range 15 to 90 minutes) and 1,3-dinitroglycerin metabolites (mean C_{max} 1 ± 0.3 ng/mL and mean t_{max} 41 ± 20 minutes, range 20 to 90 minutes).

The volume of distribution of nitroglycerin following intravenous administration is 3.3 L/kg.

A liver reductase enzyme is of primary importance in the metabolism of nitroglycerin to glycerol di- and mononitrate metabolites and ultimately to glycerol and organic nitrate. Known sites of extrahepatic metabolism include red blood cells and vascular walls. In addition to nitroglycerin, 2 major metabolites, 1,2- and 1,3-dinitroglycerin are found in plasma. The mean elimination half-life of both 1,2- and 1,3-dinitroglycerin is about 40 minutes. The 1,2- and 1,3-dinitroglycerin metabolites have been reported to possess some pharmacological activity, whereas the glycerol mononitrate metabolites of nitroglycerin are essentially inactive. Higher plasma concentrations of the dinitro metabolites, with their nearly 8-fold longer elimination half-lives, may contribute significantly to the duration of pharmacologic effect.

In the above referenced pharmacokinetic study the average initial half-lives ($T_{1/2\alpha}$) of nitroglycerin, and its 1,2- and 1,3-dinitroglycerin metabolites were estimated to be 3, 10, and 11 minutes, respectively. The half-life of disappearance of the nitroglycerin ($T_{1/2\beta}$) (5 minutes) was significantly less than the half-life of appearance ($T_{1/2\alpha}$) of the 1,2- and 1,3-dinitroglycerin metabolites suggesting the possibility of an additional compartment into which the nitroglycerin disappears from plasma prior to being metabolized into the dinitroglycerin metabolites. A second indication of this other compartment is that the appearance of nitroglycerin metabolites in plasma was delayed in some subjects, with zero plasma levels seen for 4-6 minutes after dosing. In some subjects, nitroglycerin metabolites appeared only after nitroglycerin C_{max} had been observed.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal carcinogenicity studies with sublingually administered or lingual spray nitroglycerin have not been performed.

Rats receiving up to 434 mg/kg/day of dietary nitroglycerin for 2 years developed dose-related fibrotic and neoplastic changes in liver, including carcinomas, and interstitial cell tumors in testes. At the highest dose, the incidences of hepatocellular carcinomas was 52% compared to 0% in untreated controls. Incidences of testicular tumors were 52% vs. 8% in controls. Lifetime dietary administration of up to 1058 mg/kg/day of nitroglycerin was not tumorigenic in mice.

Nitroglycerin was found to have reverse mutation activity in the *Salmonella typhimurium* strain TA1535 (Ames assay). A similar mutation in *S. typhimurium* strain was also reported for other NO donors. Nevertheless, there was no evidence of mutagenicity in an *in vivo* dominant lethal assay with male rats treated with oral doses of up to about 363 mg/kg/day or in *ex vitro* cytogenic tests in rat and dog tissues. *In vitro* cytogenetic assay using Chinese hamster ovary cells showed no chromosomal aberrations.

In a 3-generation reproduction study, rats received dietary nitroglycerin at doses up to about 408 mg/kg/day (males) to 452 mg/kg/day (females) for 5 months (females) or 6 months (males) prior to mating of the F_0 generation with treatment continuing through successive F_1 and F_2 generations. The highest dose was associated with decreased feed intake and body weight gain in both sexes at all matings. No specific effect on the fertility of the F_0 generation was seen. Infertility noted in subsequent generations,

however, was attributed to increased interstitial cell tissue and aspermatogenesis in the high-dose males.

14 CLINICAL STUDIES

In a randomized, double-blind, single-center, single-administration, placebo-controlled, 4-period cross-over study in 30 subjects with stable angina pectoris, statistically significant dose-related increases in exercise tolerance were seen following doses of 200, 400, and 800 mcg of nitroglycerin delivered by NitroMist compared to placebo.

16 HOW SUPPLIED/STORAGE AND HANDLING

Each box of NitroMist contains one glass bottle coated with red/orange transparent plastic which assists in containing the glass and medication should the bottle be shattered. Each unit contains 8.5 g (Net Content) of nitroglycerin lingual aerosol and will deliver 230 metered sprays containing 400 mcg of nitroglycerin per actuation.

NDC-0812-0032-35

- **Storage**
Store at room temperature (25°C, 77°F); excursions permitted to 15-30°C (59 - 85°F)
- **Handling**
NitroMist contains a highly flammable propellant (butane). Do not forcefully open a NitroMist bottle, do not have the container burned after use, and do not spray directly toward flames.

17 PATIENT COUNSELING INFORMATION

17.1 Interaction with PDE5 inhibitors

NitroMist should not be used in patients who are using medications for erectile dysfunction such as sildenafil, vardenafil, and tadalafil. These products have been shown to increase the hypotensive effects of nitrate drug such as NitroMist.

17.2 Administration

NitroMist is meant to be sprayed on or under the tongue at the beginning of angina or to prevent an angina attack. Treatment with nitroglycerin products such as NitroMist may be associated with lightheadedness on standing, especially just after rising from a laying or seated position. This effect may be more frequent in patients who have consumed alcohol, since alcohol use contributes to hypotension. If possible, patients should be seated when taking NitroMist. This reduces the likelihood of falling due to lightheadedness or dizziness [*see DOSAGE AND ADMINISTRATION 2.3*].

17.3 Headache

Headaches can sometimes accompany treatment with nitroglycerin. In patients who get these headaches, the headaches may indicate activity of the drug. Tolerance to headaches develops.

17.4 Flushing

Flushing, drug rash and exfoliative dermatitis have been reported in patients receiving nitrate therapy.

17.5 Container information

The NitroMist bottle should not be forcefully opened. Because NitroMist contains a highly flammable propellant (butane), do not have the container burned after use and do not spray directly towards flames. While the container is in the upright position, if the liquid reaches the top to middle of the hole on the

side of the container, a new supply should be obtained. When the liquid reaches the bottom of the hole, the remaining doses will have less than label content.

NITROMIST

nitroglycerin aerosol, spray

Product Information

Product Type		Item Code (Source)	NDC:0812-0032
Route of Administration	TRANSMUCOSAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITROGLYCERIN (UNII: G59M7S0WS3) (nitroglycerin - UNII:G59M7S0WS3)		400 ug

Inactive Ingredients

Ingredient Name	Strength
caprylic/capric diglycerol succinate ()	10400 ug in 1
peppermint oil ()	200 ug in 1
L(+)menthol ()	11 ug in 1
n-butane (UNII: 6LV4FOR43R)	22000 ug in 1

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0812-0032-35	1 in 1 BOX		
1		230 in 1 BOTTLE		

Labeler - NovaDel Pharma Inc.

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NovaDel Pharma Inc.