**How to Use Nitrolingual® Pumpspray**

Before using this product for the first time, the pump must be sprayed 5 times into the air (this is known as priming). The pump should be primed every 6 weeks to remain ready for use. If the product has not been used for 6 weeks, a prime of 1 spray is necessary.

1. **Remove the plastic cover.**
2. **Hold the container upright with forefinger on top of the grooved button.**
3. **Open the mouth and bring the container as close to it as possible.**
4. **Press the button firmly with the forefinger to release the spray onto or under the tongue. DO NOT INHALE THE SPRAY.**
5. **Release button and close mouth. Avoid swallowing immediately after administering the spray. The medication should not be expectorated or the mouth rinsed for 5 to 10 minutes following administration.**
6. **If you require a second administration to obtain relief, repeat steps 4, 5, and 6.**
7. **Replace the plastic cover.**

**WARNINGS:**

- Paradoxical bradycardia and paradoxical tachycardia may occur.
- Hypotension, especially orthostatic hypotension, may occur.

**INDICATIONS AND USAGE:**

- Nitroglycerin is indicated for acute and chronic exertional angina and shortness of breath due to coronary artery disease.
- Nitroglycerin is used in the acute treatment of hypertensive emergencies and hypertensive crises due to any cause.
- Nitroglycerin is also used in the acute treatment of unstable angina, acute coronary syndromes (unstable angina and NSTEMI), and NSTEMI.

**CONTRAINDICATIONS:**

- Nitroglycerin is contraindicated in patients who are allergic to it. Nitrolingual® Pumpspray is contraindicated in patients taking certain drugs for erectile dysfunction (phosphodiesterase inhibitors) because of the risk of lowering their blood pressure dangerously.

**DRUG INTERACTIONS:**

- Amlodipine may decrease the blood pressure-lowering effect of nitrates.
- Alcohol may enhance sensitivity to the hypotensive effects of nitroglycerin.

**WARNINGS:**

- Paradoxical bradycardia and paradoxical tachycardia may occur.
- Hypotension, especially orthostatic hypotension, may occur.

**ADVERSE REACTIONS:**

- The most common adverse reactions associated with nitroglycerin use are headache, hypotension, and dizziness.

**PRECAUTIONS:**

- The use of nitroglycerin is associated with a risk of hypotension and orthostatic hypotension.

**CLINICAL PHARMACOLOGY:**

- Nitroglycerin is a nitrate vasodilator that acts rapidly to dilate blood vessels and reduce blood pressure. It is used to treat angina pectoris, congestive heart failure, and hypertension.

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observed: at various doses of nitroglycerin, the following adverse effects have been
particularly headache and hypotension, are generally dose-related. In clinical trials
Adverse reactions to oral nitroglycerin dosage forms, PEDIATRIC USE:
363 mg/kg/day, p.o., or in
In a three-generation reproduction study, rats received dietary nitroglycerin at
response with treatment continuing through successive F1 and F2 generations. The high
es were seen at any dose tested. There are no adequate and well-controlled studies
increased interstitial cell tissue and aspermatogenesis in the high-dose males. In
Spray should be administered to a nursing woman. Nitroglycerin should be given to pregnant women only if clear-
was seen. Infertility noted in subsequent generations, however, was attributed to
Storage at 25 °C (77 °F); excursions permitted to 15-30 °C (59-86 °F) [see USP Controlled Room Temperature].
Manufactured for FIRST HORIZON PHARMACEUTICAL® CORPORATION, Alpharetta, GA 30005 by G.Pohl-Boskamp GmbH & Co. KG, D-23551 Hohenlockstedt, Germany.

May be required. If an excessive quantity of Nitrolingual® Pumpspray has been
Then an immediate intravenous infusion of 20% mannitol, 0.1-0.3 mg/kg of body weight methylen blue (1% solution), 1-2 mg per kilogram of body weight intravenously,

Methemoglobinemia: intracranial pressure with cerebral symptoms of confusion and moderate fever,

Adverse events occurring at a frequency greater than 2% included: headache,

WARNING: Drug rash and/or exfoliative dermatitis occurring at a frequency greater than 1% in clinical trials is usually characterized by eruptions of purpuric or pemphigiform lesions, as well as painful skin lesions, which are generally associated with constitutional symptoms of fever, skin tenderness, and increased excretion of urine. Although severe and life-threatening, these reactions are usually reversible when drug is withdrawn and treatment is continued. The incidence of this type of reaction is increased in individuals with a history of atopy or eczema. A similar reaction, purpuric or pemphigiform, may be precipitated by exposure to antibacterials (penicillins, sulfonamides, tetracyclines), or to anticonvulsants (phenobarbital, mephénytoïne). Extreme caution and observance of the proper use of these drugs are recommended in patients who have had a previous reaction to nitroglycerin, with or without evidence of methemoglobinemia (see Precautions).

When Nitrolingual® Pumpspray is administered to a nursing woman.

inhibits the cGMP-specific phosphodiesterase enzyme, resulting in the accumulation of cGMP within the smooth muscle cells of the arteries, leading to vasodilation and a decrease in blood pressure. This effect is dose-dependent and can be reversed by the administration of vasoconstrictors such as phenylephrine or norepinephrine. Excessively high arterial pressure at the onset of nitroglycerin exposure may lead to systemic hypotension. Some patients may respond with a marked decrease in blood pressure, which could precipitate syncope.

In several studies, nitroglycerin has been shown to be effective in reducing the frequency and severity of anginal episodes and to improve exercise tolerance in patients with stable angina. It is also effective in the acute treatment of anginal attacks. Intravenous nitroglycerin has been used to treat acute coronary syndromes, including unstable angina and non-ST elevation myocardial infarction. Nitroglycerin is also used to treat hypertension and to prevent angina during exercise or during the postoperative period. It is also used to decrease the intensity of the pain of coronary artery disease.

Adverse reactions occurring at a frequency greater than 2% included: headache, during an anginal attack, one or two sprays should be administered into your mouth, preferably

DOSAGE AND ADMINISTRATION: In the event of an attack, one or two metered

DOSEAGE AND ADMINISTRATION: The dose of nitroglycerin should be adjusted individually to the patient's needs, with the goal of achieving adequate relief of symptoms with the lowest possible dose. The initial dose may be 400 mcg of nitroglycerin after an initial priming of 5 sprays. The container will remain adequately primed for 6 weeks. If the medication is not used within 6 weeks, it can be adequately reprimed with 1 spray.

Storage guidelines recommend us to store the product at 25 °C (77 °F) and not to exceed 30 °C (86 °F). The product should be protected from light and moisture. When the product is not in use, it should be stored in the original packaging to maintain its potency. The product should not be exposed to temperatures above 30 °C (86 °F) or below 2 °C (36 °F).

Later becoming cold and cyanotic, nausea and vomiting (possibly with

Nitroglycerin should not be administered to patients with a history of methemoglobinemia, as this can cause life-threatening reactions. Precautions should also be taken in patients with a history of allergies to aspirin, penicillin, or other antibiotics, as these reactions can be exacerbated by the use of nitroglycerin.

Upon the administration of nitroglycerin, the patient may experience flushing, a feeling of heat, or a sensation of warmth. These symptoms are usually transient and are not considered to be adverse effects. However, in some patients, these effects may be severe and require the discontinuation of therapy.

Adverse effects occurring at a frequency greater than 2% included: headache,

The nitroglycerin solution is stored in a clear, plastic, transparent container designed to protect the medication from light and air exposure. The container is attached to a metal nozzle, making it easy to administer the medication. The spray mechanism is activated by pressing the button on the nozzle, which delivers a precise and controlled dose of nitroglycerin. The dosage is dependent on the number of sprays per use, which is typically one or two sprays for the treatment of anginal attacks.

Nitroglycerin is a nitrate derivative that works by relaxing smooth muscle in blood vessels, leading to increased blood flow and reduced blood pressure. This effect is dose-dependent, meaning that increasing the dose will increase the effect on blood flow. Nitroglycerin is used to treat anginal attacks, to prevent angina during exercise, and to treat hypertension. It is also used to decrease the intensity of the pain of coronary artery disease.

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