**Nitrolingual® Pumpspray**

**WARNINGs AND PRECAUTIONS**

Nitrolingual® Pumpspray is contraindicated in patients who are allergic to nitroglycerin, other nitrates or nitrites or any excipient.

**INDICATIONS AND USAGE**

Nitrolingual® Pumpspray is indicated for patients with coronary artery disease who experience symptomatic episodes of angina pectoris due to coronary artery disease.

**DOSAGE AND ADMINISTRATION**

**2.1 Recommended dosage**

Use of phosphodiesterase type 5 (PDE5) inhibitors, such as avanafil, sildenafil, and vardenafil, is not recommended within a 24-hour period following the use of Nitrolingual Pumpspray.

**2.2 Priming**

Step 1. Hold the container upright and press the button for priming 5 to 10 times. A hissing sound should be heard, and the spray orifice, which can be identified by the finger groove, should be seen. The pump must be primed prior to the first use. Each time the Nitrolingual Pumpspray is put down, it must be primed again. It is not necessary to prime Nitrolingual Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**2.3 Administration**

Instruct patients that during administration, the patient should remain seated and not stand up immediately after each dose. Nitrolingual Pumpspray is intended for self-administration. To ensure effectiveness, the spray orifice, which can be identified by the finger groove, should be seen.

**ADVERSE REACTIONS**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**4.5 Circulatory failure and shock**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**5.4 Headache**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**5.2 Hypotension**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**5.1 Tolerance**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**4.1 PDE-5-Inhibitors and sGC-Stimulators**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**7.3 Ergotamine**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**4.3 Hypertensive crisis and stroke**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**4.4 Hypersensitivity**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**5.5 Neurologic: weakness, drowsiness**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**5.1 Tolerance**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**4.6 Other adverse reactions**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**7.1 PDE-5-Inhibitors and sGC-Stimulators**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**7.2 Antiplatelet agents**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**7.3 Ergotamine**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**4.2 Severe anemia**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**4.5 Circulatory failure and shock**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
- Valve head
- Container

**5.4 Headache**

Nitrolingual® Pumpspray parts:

- Grooved button
- Actuator
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- Container

**5.2 Hypotension**

Nitrolingual® Pumpspray parts:

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**5.1 Tolerance**

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**4.6 Other adverse reactions**

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**5.1 Tolerance**

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**4.6 Other adverse reactions**

Nitrolingual® Pumpspray parts:

- Grooved button
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- Valve head
- Container
Nitrolingual Pumpspray.

If the level of the fluid falls below the end of the
container regularly.

or rinse your mouth for 5 to 10 minutes after using
Pumpspray. Do not spit out Nitrolingual Pumpspray
away. Avoid swallowing right after using Nitrolingual
Release the grooved button and close your mouth right
the dark.

you are administering the spray in

Help you make sure the canister

Giving a dose of Nitrolingual Pumpspray:

Step 5.

Step 4.

your index finger on top of the grooved button.

Hold your Nitrolingual Pumpspray container upright with

Giving a dose of Nitrolingual Pumpspray:

12.1 Mechanism of action

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of action

The principal pharmacological action of nitroglycerin
activates guanylate cyclase, resulting in an increase of
1,3-dinitroglycerin is about 40 minutes. The 1,2- and
possess some pharmacological activity, whereas the
crown arteries; however, the extent to which this


CH

The chemical structure is:

Nitroglycerin, an organic nitrate, is a vasodilator which

11 DESCRIPTION

11  DESCRIPTION

Nitroglycerin was weakly mutagenic in Ames tests
administration of up to 1058 mg/kg/day of nitroglycerin
Methylene Blue

11 DESCRIPTION

Nitroglycerin forms free radical nitric oxide (NO), which
drugs, beta-

7.2 Antihypertensives

- [ ] and well-controlled studies in pregnant women.

7.2 Antihypertensives

Patients receiving antihypertensive drugs, beta-

- and well-controlled studies in pregnant women.

8.3 Nursing mothers

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and well-controlled studies in pregnant women.

8.1 Pregnancy

8.1 Pregnancy

Oral administration of nitroglycerin markedly decreases
depressed. Patients should be instructed to consult their
physicians if the dosage or frequency of nitroglycerin
sprays becomes necessary. Definitions: Life-threatening
hypotension is characterized by symptoms such as
profuse sweating, nausea, clammy skin and a rapid, weak
pulse. Hypotension is characterized by symptoms such as
dizziness, lightheadedness and a normal pulse. A cutaneous
reaction of methylene blue (1 % solution), 1 – 2 mg per

10.1 Signs and symptoms, methemoglobinemia

Methemoglobin formation occurs at doses up to 80 mg/kg/day and 240 mg/kg/day,
conducted with topically applied nitroglycerin ointment
not been conducted with Nitroglycerin Pumpspray.

8.1 Pregnancy

–[ ] pregnancy exposures and all relevant information
and well-controlled studies in pregnant women.

8.1 Pregnancy

No toxic effects on dams or fetuses were
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8.3 Nursing mothers

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8.1 Pregnancy

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ossification were seen. The latter finding probably

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The drug showed a profile of mild to moderate adverse
tolerance, time to onset of angina and ST-segment
capillary leakage.

14 CLINICAL STUDIES

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In a randomized, double-blind single-dose, 5-period
cross-over study in 51 patients with exertional angina

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