INDICATIONS AND USAGE

GONITRO™ (GO-NYE-troh) (nitroglycerin) sublingual powder, in packets containing individual packets of 1 mg (400 mcg) or 2 mg (800 mcg) of nitroglycerin, is a medication indicated for the relief of angina pectoris due to coronary artery disease. It is for use under the tongue and is a non-nitrate, non-opioid medication for the treatment of acute angina attacks.

DOSE FORMS AND STRENGTHS

3 mg (1 packet of 2 mg, 1 packet of 1 mg)

CONTRAINDICATIONS

GONITRO is contraindicated in patients who are taking PDE-5-inhibitors, such as avanafil, sildenafil, tadalafil, or vardenafil, or are using any guanylate cyclase (sGC) stimulators, such as riociguat.

Adverse reactions occurring at a frequency greater than 2 % in clinical trials of another drug and may not reflect the rates in clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug.

ADVERSE REACTIONS

Adverse reactions associated with the use of GONITRO are common and include hypotension, headache, flushing, and paresthesia.

HEADACHE

Inhibitors, such as avanafil, sildenafil, tadalafil, or vardenafil. Do not use GONITRO in patients taking PDE-5-inhibitors. Do not use GONITRO in patients with acute circulatory failure and shock.

ADVERSE REACTIONS

GONITRO may be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack. (2.1)

INDICATIONS AND USAGE

FULL PRESCRIBING INFORMATION

Instructions for Use of GONITRO™ (GO-NYE-troh) (nitroglycerin) sublingual powder

Read these Instructions for Use before you start using GONITRO and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Important Information:

GONITRO™ is for use under the tongue. A dose of 0.5 mg (1 packet) should be used either one or 2 packets. Follow your healthcare provider’s instructions. Do not repeat dosing. If you must take more than 1 packet, you may take additional packets of GONITRO every 5 minutes. Do not exceed 3 packets. Some may recommend taking a total of 3 packets of GONITRO.

1 INDICATIONS AND USAGE

1.1 Full Prescribing Information

5.1 Tolerance

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5.1 Tolerance

5.2 Temporary Excess of Nitroglycerin

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5.3 Hypertrophic Obstructive Cardiomyopathy

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5.4 Headache

5.4 Headache

5.5 Angina

5.5 Angina

5.6 Cardiovascular collapse

5.7 Respiratory failure

5.8 Nausea

5.8 Nausea

5.9 Other symptoms

5.10 Other symptoms

5.11 Other symptoms

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The chemical structure is: CH₂–ONO₂

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy

10.2 Treatment of Overdosage

10.1 Signs and Symptoms, Methemoglobinemia

The results of the study indicate that the sublingual administration of GTN is higher following the administration of GTN in healthy volunteers (n = 32), the mean C max and t max for GTN were 12,300 pg/mL ∙ min.

In a pharmacokinetic study a single 800 mcg dose of nitroglycerin was administered to 15 healthy volunteers (10 male, 5 female) aged 65 and over to determine whether they respond differently to GTN as compared to younger persons. The group of subjects 65 years or older included persons with hypertension, diabetes, congestive heart failure, and chronic obstructive pulmonary disease. The mean C max for GTN was 12,300 pg/mL ∙ min. In animal reproduction studies, no evidence of fetal toxicity was observed in rats and rabbits when administered to the dam at doses up to 100 times the maximum human dose (based on mg/m²).

In a three-generation reproduction study, rats received nitroglycerin for 28 days prior to mating and throughout gestation, lactation, and weaning. The highest dose administered was 4 mg/kg/day for 13 days.

Oral administration of nitroglycerin markedly decreases the time to onset of angina and ST-segment depression were 12,300 pg/mL ∙ min. For GTN was 12,300 pg/mL ∙ min.

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