PATIENT PACKAGE INSERT IN ACCORDANCE
WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a physician's prescription only

Nitrolingual Spray

Composition
Active ingredient:
Each dose contains:
0.4 mg Glyceryl Trinitrate

Each dose contains 9.600 mg ethanol.

For the list of inactive ingredients and allergens in the medicine: See section 2 under "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, consult your physician or pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Medical activity: Relief of angina pectoris attacks, angina pectoris prophylaxis.

Therapeutic group: Nitrates, vasodilators.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient Glyceryl Trinitrate, nitrates or any of the additional ingredients contained in the medicine (see section 6 "Additional information").
  An allergic reaction may include a rash, itchiness, breathing difficulties or swelling of the face, lips, throat or tongue.
- You suffer from: a severe circulatory problem, very low blood pressure (below 90 mm of mercury) or severe loss of blood; if you had an acute cerebrovascular accident, cerebral hemorrhage, severe head trauma or acute anemia.
- You suffer from **unusual heart conditions** such as acute circulatory shock (where there is impaired blood flow to the body's tissues), this can include hypovolemic shock (as a result of low blood volume), uncontrolled cardiogenic shock (as a result of decreased cardiac output), severe mitral stenosis (narrowing of the opening of the mitral valve in the heart) or obstructive cardiomyopathy (a disease of the heart muscle causing obstruction of blood flow).

- If you are taking **Viagra** (sildenafil) or similar preparations (e.g., vardenafil, tadalafil) for treatment of erectile dysfunction or pulmonary arterial hypertension concurrently with use of **Nitrolingual Spray**, there is a substantial risk of a severe drop in blood pressure which can result in possibly fatal collapse and loss of consciousness.
- The medicine is not intended for use in children and infants.

Special warnings regarding use of the medicine
Before starting treatment with Nitrolingual Spray tell your physician if:

- You are in the early stages of glaucoma (elevated intraocular pressure).
- You suffer from aortic and/or mitral valve stenosis (narrowing of the opening of the aortic or mitral valve.)
- You feel dizzy if you sit or stand upright suddenly.
- You suffer from cerebrovascular diseases.
- You suffer from pericardial tamponade (compression of the heart muscle caused by blood or fluid accumulation in the space between the heart muscle and the pericardium.)
- You suffer from constrictive pericarditis.
- You suffer from low blood oxygen levels in cases of lung disease or pulmonary heart disease (enlargement of the right ventricle of the heart).
- You have had a heart attack.
- You suffer from left ventricular hypertrophy (thickening of the heart muscle in the left ventricle) associated with aortic stenosis (narrowing of the opening of the aortic valve.)
- You suffer from moderate to severe aortic stenosis (narrowing of the aortic valve).

    - Consult with your physician if after using **Nitrolingual Spray** the pain does not stop, lasts longer than usual (a half hour or more) or feels different or worse than usual.

Drug interactions:
Tell your physician or pharmacist if you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, because taking two or more medicines concurrently may strengthen or weaken the effect of the medicine. Especially inform your physician or pharmacist if you are taking:

- Preparations for treating erectile dysfunction or pulmonary arterial hypertension (see section 2 – Before using the medicine)

- Preparations which are liable to cause a drop in blood pressure such as beta-blockers, calcium channel blockers, antipsychotic medicines,

vasodilators, antihypertensives, diuretics, tricyclic antidepressants, sapropterin (for treating HPA)

- Anticoagulants such as heparin
- N-acetyl-cysteine.

If you use **Nitrolingual Spray** very frequently or if you regularly use other nitrates, the pain relief may be reduced.
During use with dihydroergotamine, used to treat migraines, **Nitrolingual Spray** may lead to increased dihydroergotamine levels, thereby increasing blood pressure.

Use of the medicine and alcohol consumption:
If you drink alcohol before using **Nitrolingual Spray**, you may feel dizzy or faint due to low blood pressure.

Pregnancy, breastfeeding and fertility:
Pregnancy
Tell your physician if you become pregnant while taking **Nitrolingual Spray.**
You should use **Nitrolingual Spray** only after discussing with your physician the expected benefit versus the potential risks for your unborn child.
Breastfeeding
It is not known whether Glyceryl Trinitrate passes into breast milk. You should consult with your physician if you are breastfeeding or are interested in breastfeeding.
Fertility
There is no evidence of a harmful effect on fertility.

Driving and operating machinery:
Using the medicine may impair alertness, and therefore caution must be exercised when driving a vehicle, operating dangerous machinery and performing any activity which requires alertness.
You should wait at least five minutes after using **Nitrolingual Spray** before driving or operating machinery.
If you feel dizzy or unwell or feel that you are about to faint, wait until you feel better. You should be especially careful when starting treatment with **Nitrolingual Spray,** when changing the dose or transitioning from another medicine, or when using together with alcohol.

Important information about some of the medicine's ingredients:
Each dose contains 9.600 mg of ethanol, less than 10 mg per puff.
Do not store or spray near inflammable material.

3. How should you use the medicine?

Always use the preparation according to your physician's instructions. You should check with your physician or pharmacist if you are unsure about the dosage or treatment regimen for the preparation.

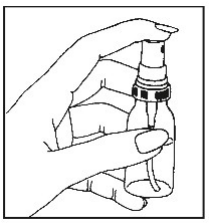
The dosage and treatment regimen will be determined by your physician only.

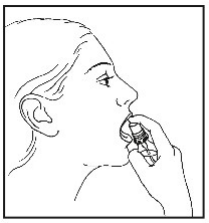
- Unless prescribed otherwise by the physician, the usual dose is generally:

Adults:
At the onset of an attack of angina pectoris or just prior to an event known to likely precipitate an attack of angina pectoris:
Spray one or two puffs of the spray **under the tongue** (each puff contains a dose of 400 micrograms of Glyceryl Trinitrate). If symptoms do not resolve, this may be repeated at five-minute intervals for a total of three puffs. If symptoms have not resolved, you should seek immediate medical treatment.
Children:
No data are available on the safety and efficacy of using this preparation in children.

Method of administration:
Before using the medicine:
Hold the bottle vertically with the spray orifice uppermost. Before using a new bottle of **Nitrolingual Spray** for the first time or if you have not used the preparation for over a week, spray the first puff into the air. Then place the spray orifice as close as possible to the mouth. Spray the dose under the tongue and close the mouth immediately after each puff. Do not inhale the spray.
In order to make it easier to use the preparation at night, familiarise yourself in advance with the position of the spray orifice, which can easily be identified by the grooved finger rest on the button.
When using the preparation you should be at rest, preferably in a sitting position, due to the risk of postural hypotension, a situation where a drop in blood pressure occurs after getting up from a recumbent or sitting position. Hypotension and syncope can be a particular problem with the use of nitrates in the elderly.

Do not exceed the recommended dose





If you have accidentally taken a higher dosage you may experience more severe and pronounced side effects (see section 4 “Side effects”), e.g., severe headache, blurred vision, feeling flushed, and a slow heart rate. You may also

feel faint, sweaty, short of breath, weak, restless and feel sick or be sick, or notice a bluish tint around the lips or a bluish colouration of your skin. In rare cases you may develop methemoglobinemia (a disorder of the red blood cells). If any of these effects persists, consult your physician or pharmacist. If you took an overdose or if a child accidentally swallowed the medicine, consult a physician immediately or proceed to a hospital emergency room and bring the medicine's packaging with you.

Adhere to the treatment regimen as recommended by your physician. Even if there is an improvement in your health condition, do not stop treatment with this medicine without consulting your physician. Consult with your physician or pharmacist if you feel that the medicine's effect is either too weak or too strong.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult your physician or pharmacist.

4. <u>Side effects</u>

As with all medicines, the use of **Nitrolingual Spray** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

<u>Very common side effects - effects that occur in more than one user in ten:</u>

- Headaches

<u>Common side effects – effects that occur in 1-10 users in 100:</u>

- Low blood pressure when standing (a sudden drop in blood pressure caused by a change in posture, such as when standing up quickly)
- Decreased blood pressure
- Weakness
- Dizziness
- Drowsiness
- Increased heart rate

<u>Uncommon side effects - effects that occur in 1-10 users in 1,000:</u>

- Fainting
- Worsened angina symptoms
- Slowed pulse
- Blue discolouration
- Facial skin flushing
- Circulatory collapse (a problem with the blood circulatory system)
- Nausea
- Vomiting
- Allergic skin rash

- Hypersensitivity

Very rare side effects – effects that occur in less than one user in 10,000:

- Cerebral ischemia (decreased blood flow to the brain)
- Methemoglobinemia (a red blood cell disorder)
- Confusion and restlessness
- Breathing difficulty
- Peeling skin and skin rash

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Tongue swelling (due to an allergic reaction)
- Tongue blistering

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the homepage of the Ministry of Health website (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. How should the medicine be stored?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your physician.
- Do not use the medicine after the expiry date (exp. Date) appearing on the package. The expiry date refers to the last day of that month.
- Do not discard medicines in wastewater or in household waste. Ask the pharmacist about how to discard medicines which you are no longer using. These measures will help protect the environment.

Storage conditions:

- Store at a temperature that does not exceed 25°C.

6. Additional information

- In addition to the active ingredient (Glyceryl Trinitrate) the medicine also contains:
  medium-chain triglyceride, ethanol anhydrous, glycerol monocaprylocaprate, peppermint oil, purified water, sodium (S)-lactate solution 50%, (S)-lactic acid 90%
- What the medicine looks like and what the package contains:

Each bottle contains 6.3 g / 13.2 g / 15.4 g - of clear, colorless to yellowish solution.

Not all package sizes may be marketed.

- **Registration holder and address:** Megapharm Ltd., 15 HaTidhar St., Ra'anana, Israel.
- **Manufacturer and address:** G. Pohl-Boskamp, Hohenlockstedt, Germany.
- Revised in November 2024 according to Ministry of Health guidelines
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:103-04-27820