

PACKAGE LEAFLET: INFORMATION FOR THE USER

NITROGLICEROL

2.5 mg, prolonged-release capsules, hard

GLYCEROL TRINITRATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Nitroglicerol is and what it is used for
2. Before you take Nitroglicerol
3. How to take Nitroglicerol
4. Possible side effects
5. How to store Nitroglicerol
6. Further information

1. WHAT NITROGLICEROL IS AND WHAT IT IS USED FOR

NITROGLICEROL capsules contain the active substance glycerol trinitrate.

Glycerol trinitrate acts relaxingly on the smooth muscles of the blood vessels causing the blood vessels to widen (vasodilatation). In this way, it increases the blood flow through the heart and supplies the heart muscle with oxygen, and reduces the load on the heart.

NITROGLICEROL capsules are applied for preventing attacks of pain in the chest (prevention of angina pectoris).

2. BEFORE YOU TAKE NITROGLICEROL

Alert the doctor if you are taking other medicines, you have a chronic disease, a metabolic disorder, hypersensitive you are on medicine or have had an allergic reaction to some of them.

Do not use NITROGLICEROL capsules

- If you are allergic (hypersensitive) to glycerol trinitrate, or to any of the other substances in NITROGLICEROL capsules (see section 6);

- If you are allergic (hypersensitive) to nitric compounds;
- If you have increased intracranial pressure (pressure in the head) due to bleeding in the brain or head injury;
- If you have hypertrophic obstructive cardiomyopathy (heart muscle increase followed by decreased blood flow)
- If you have severe anemia;
- If you have a very low blood pressure and decreased blood volume;
- If you are taking medicine for the treatment of sexual impotence (sildenafil and vardenafil) and pulmonary arterial hypertension (tadalafil) (see section "taking other medicines with NITROGLICEROL capsules");
- If you have an acute attack of angina pectoris;
- If you have a narrowing (stenosis) of the aorta (the arteries in your heart), and/or mitral heart valve disease.

Be careful with NITROGLICEROL capsules

- NITROGLICEROL capsules should be used with caution in the elderly, in patients with hepatic and renal impairment, impaired function of the thyroid gland and decreased body temperature (hypothermia), in patients with a risk of a sudden increase in eye pressure (glaucoma, closed angle), and in patients after a recent heart attack (myocardial infarction).
- It is necessary to avoid the sudden change from a lying to a standing position, to avoid excessive reductions in blood pressure.
- Treatment should not be abruptly interrupted because there could be a severe attack of angina pectoris. If the treatment has to stop, it is necessary to gradually reduce the dose according to the instructions of your doctor.
- In patients who suffer from the increased mobility of the intestine (Gastrointestinal hypermotility) or the syndrome of inadequate absorption of nutrients; it is recommended to avoid the use of medicine with prolonged-release.
- During the application of NITROGLICEROL capsule you can develop tolerance (decrease of action) to this medicine, as well as cross tolerance to other nitrates. If during prolonged treatment you get the impression that the medicine has lost the efficacy, you should notify your doctor.

Taking other medicines with NITROGLICEROL capsules

Keep in mind that this information can apply to medicines that you no longer take, as well as to the medicine that you are planning to take in the future. Inform your doctor if you are taking, or have recently taken any other medicine, including the medicine purchased without a prescription.

- Alcohol can further lower your blood pressure, and should not be consumed during the course of therapy.
- Aspirin increases the concentration of glycerol trinitrate and further reduces the accumulation of platelets (platelet aggregation).
- concomitant use of water tablets (diuretics), other medicines for lowering blood pressure (antihypertensives and vasodilators) with NITROGLICEROL capsules can further lower your blood pressure;
- Specifically, the concomitant use of medicines for the treatment of sexual impotence (sildenafil, vardenafil) and pulmonary arterial hypertension (tadalafil) can lead to severe reduction of your blood pressure. Because of this, NITROGLICEROL capsules should not be taken at the same time with these medicines (see section "do not use NITROGLICEROL capsules").
- NITROGLICEROL capsules can raise the value of Dihydroergotamine (migraine therapy), which may result in a worsening of the symptoms of angina pectoris.

Taking food and drinks with NITROGLICEROL capsules

We do not recommend alcohol consumption during the course of treatment with NITROGLICEROL capsules.

Pregnancy and breastfeeding

Before you begin to take some medicine, you should consult with your doctor or pharmacist.

Pregnancy

The medicine may be administered during pregnancy only if the doctor determines that the potential benefit for the mother exceeds potential risk to the fetus.

Breast feeding

The use of this medicine during the period of breastfeeding is not recommended.

Driving and using machines

The medicine can cause a drop in blood pressure and dizziness, and thus affect the ability to drive motor vehicles and/or use machines. This is especially pronounced at the beginning of the therapy, when you increase the dose of the medicine, and during simultaneous alcohol consumption.

Other warnings

NITROGLICEROL capsules contain lactose and sucrose (sugar).

If your doctor earlier said you have intolerance to some sugars, before you start using this medicine, consult your doctor.

3. HOW TO TAKE NITROGLICEROL

Apply the medicine according to the enclosed instructions. If you think that the action of the medicine is too strong or too weak, talk to your doctor or pharmacist.

Method of administration

The capsules should be swallowed whole with enough fluid, on an empty stomach, 1 hour before or 2 hours after a meal.

Dosing

The dose is always determined by your doctor.

Typically, treatment starts with low doses that are then gradually increase as needed.

Only your doctor can decide on increasing the dose or changing the frequency of application.

With long-term use of NITROGLICEROL capsules, the effect can be reduced. In order to avoid weakening or loss of medicinal activity, your doctor will choose the lowest effective dose and try to accomplish period without nitroglycerin for at least 10 hours during the day.

Adults

Prevention of attacks of chest pain (prevention of angina pectoris): 2.5 to 5 mg (1 to 2 NITROGLYCERIN capsule) three times a day.

Children

NITROGLICEROL capsules are not intended for use in children.

If you take more NITROGLICEROL capsules than you should

If you have taken a larger amount of medicine than prescribed, immediately contact your doctor, or pharmacist.

If you have taken too much NITROGLICEROL capsules, contact your doctor. Symptoms of overdose are pronounced fall in blood pressure, methemoglobinemia, which follows the bluish coloration of the skin and mucous membranes, and loss of consciousness.

In case of overdose, patients should be placed in a recumbent position with the feet up and immediately transported to the clinic for emergency treatment, where other first-aid measures will be applied (gastric lavage, control of vital functions).

If you forget to take NITROGLICEROL capsules

If you forget to take a dose, take your next dose at the usual time. Do not take a double dose to make up for a missed dose.

If you have any further questions on the use of NITROGLICEROL capsules, contact your doctor, or to the pharmacist.

If you stop taking NITROGLICEROL capsules

Take this medicine for as long as your doctor has prescribed.

Do not stop treatment abruptly because there could be a severe angina pectoris attack. If the treatment has to stop, it is necessary to gradually reduce the dose according to the instructions of your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, NITROGLICEROL capsules can cause unwanted effects.

Disorders of the nervous system:

Very common: at the beginning of treatment it may cause headaches that usually disappear in the continuation of treatment.

Common: Vertigo

Uncommon: syncope (loss of consciousness)

Cardiovascular disorders:

Common: postural hypotension (fall in blood pressure when changing position from lying to standing), tachycardia (increased heart rate).

Uncommon: transient hypoxemia (low oxygen content in the blood), transient redness of the face.

Rare: paradoxical bradycardia (abnormally reduced heart rate).

Gastrointestinal disorders:

Uncommon: heartburn, nausea, vomiting.

Disorders of the skin:

Uncommon: allergic skin reactions.

Disorder of senses:

Very rare: closed angle glaucoma.

If any of these side effects get serious, or you notice a side effect that is not specified in this manual, please inform your doctor or pharmacist.

5. HOW TO STORE NITROGLICEROL

Keep out of reach and sight of children.

Keep at temperature up to 25 ° c.

Shelf life: 36 months

NITROGLICEROL capsules should not be used after the expiry date stated on the carton.

6. FURTHER INFORMATION

What NITROGLICEROL contains

One NITROGLICEROL capsule, hard contains: Glycerol trinitrate 2.5 mg

NITROGLICEROL capsules contain the following auxiliary substances: sugar, talc, shellac, sucrose, lactose, and povidone.

The composition of the capsules: titanium dioxide (E 171), Sunset Yellow FCF (E110), Ponceau 4R (E124) and gelatin.

What NITROGLICEROL capsules look like and contents of the pack

NITROGLICEROL capsules are oblong, hard gelatin capsules made up of body and cap. Body of capsule is white in color; cap of the capsule is orange. The content of the capsule is a mixture of pelega cream white to grey-white in color.

NITROGLICEROL capsules are packaged in boxes with 20 capsules (2 blisters with 10 capsules).

Regime of dispensing

The medicine is issued on doctor's prescription

Marketing authorization holder

Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina

Manufacturer of the medicinal product

Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina