

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.

NITRAX 40 mg prolonged release tablets

NITRAX 60 mg prolonged release tablets

Isosorbide mononitrate

What is in this leaflet

1. What **NITRAX** is and what it is used for
2. What you need to know before you take **NITRAX**
3. How to take **NITRAX**
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1. What NITRAX is and what it is used for

NITRAX tablets contain the active substance isosorbide mononitrate (ISMN). ISMN belongs to a group of medicines called organic nitrates.

NITRAX prolonged release tablets are used to prevent attacks of angina (chest pain). **NITRAX** works by opening up blood vessels and reducing the pain.

2. What you need to know before you take NITRAX

Do not take NITRAX:

- if you are allergic to isosorbide mononitrate or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from increased intracranial pressure (high pressure within your skull, e.g. from a blow to your head) or cerebral haemorrhage – bleeding from a ruptured blood vessel in the brain
- if you are taking sildenafil or similar products e.g. Viagra for male erectile dysfunction
- if you are taking riociguat e.g. Adempas for pulmonary hypertension
- if you have been diagnosed with any of the following:
 - hypertrophic obstructive cardiomyopathy (HOCM),
 - constrictive pericarditis,
 - cardiac tamponade or aortic/mitral valve stenosis.
- if you have very low iron levels in your blood (severe anaemia)
- if you suffer from high pressure in the eye (closed angle glaucoma)
- if you have low blood pressure

Warnings and precautions

Talk to your doctor or pharmacist before taking **NITRAX**:

- if you suffer from malnutrition
 - if you suffer from hypothermia (body temperature which is lower than normal)
 - if you are pregnant, think you might be pregnant, considering becoming pregnant or are breast feeding
 - if you have severe liver or kidney disease
 - if your thyroid gland is underactive or you are taking thyroxine
 - if you have recently suffered from a heart attack
 - if you are taking any other medication, even those you may have bought for yourself without prescription
- NITRAX** should not be used for the relief of sudden (acute) attacks of angina. If you have an attack of angina you should speak to your doctor or pharmacist who may supply you with other medicines for this.

Other medicines and NITRAX

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

NITRAX may lower blood pressure (you may experience

this as dizziness, tiredness or feeling sick) so take special care when taking other medicines that may also lower blood pressure.

Do not take **NITRAX** if you are taking riociguat, e.g. Adempas for pulmonary hypertension. When taken together a fall in blood pressure can occur.

Do not take **NITRAX** if you are taking sildenafil or similar products, e.g. Viagra for male erectile dysfunction. When taken together a severe and possibly dangerous fall in blood pressure can occur, which may result in collapse, unconsciousness and could be fatal.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines taken without a prescription.

NITRAX with alcohol

You are advised NOT to drink alcohol with this medicine, as the effects of alcohol may become worse. Alcohol may also increase the side effects of this medicine and make you feel dizzy or light-headed if you stand up or move suddenly.

Pregnancy and breast-feeding

In pregnancy or when breast feeding, **NITRAX** should only be used under medical supervision. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Do not drive or operate machinery when taking **NITRAX** if you develop low blood pressure (you may experience this as dizziness, tiredness or feeling sick) or if you have blurred vision.

NITRAX contains lactose.

Lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **NITRAX**.

3. How to take NITRAX

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Very occasionally, some people see the remains of the tablet in their bowel motions. This is quite normal and does not mean the medicine has not been released.

Adults and the elderly

1 or 2 tablets daily, ideally in the morning.

Swallow **NITRAX** tablets whole with water. Do not crush or chew.

Children

NITRAX must not be given to children.

Treatment duration

Angina pectoris requires long-term therapy. Do not stop taking **NITRAX** until your doctor tells you.

If you take more **NITRAX** than you should

You should only take what your doctor recommends. If you take too many **NITRAX** tablets contact your doctor or pharmacist if you can do so. If not, go to the nearest hospital casualty department immediately,

taking the **NITRAX** pack and remaining tablets with you.

If you have taken more **NITRAX** than you should, symptoms may include nausea, vomiting, restlessness, confusion, warm flushed skin, blurred vision, headache, fainting, fast heart beats and palpitations.

If you forget to take **NITRAX**

If you forget to take your tablet, take it as soon as possible and continue to take the tablets as normal. Do not take a double dose to make up for a forgotten tablet.

If you stop taking **NITRAX**

Angina is a condition which may need treatment for life, always talk to your doctor or pharmacist before stopping using **NITRAX**.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, **NITRAX** can cause side effects, although not everybody gets them.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- Headaches may occur when treatment is first started but usually disappear after 1 to 2 weeks.
- Low blood pressure may occasionally occur (you may experience this as dizziness, faintness on standing, tiredness and feeling sick).
- More rarely, becoming flushed and allergic reactions (including rashes) can occur.
- Increased and decreased heart rate have also been reported.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store NITRAX

Do not store above 25°C. Store in the original pack to protect from moisture.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What NITRAX contains

The active substance is isosorbide-5-mononitrate (each tablet contains 40 or 60 mg of the active substance).

The other ingredients are:

hydroxypropylmethylcellulose, lactose monohydrate, silicon dioxide colloidal and magnesium stearate.

Contents of the pack

30 (3x10) tablets 40 mg in a blister pack, in a box.

30 (3x10) tablets 60 mg in a blister pack, in a box.

Marketing Authorisation Holder and Manufacturer:

ZADA Pharmaceuticals d.o.o.

Donji Bistarac bb

75300 Lukavac, Bosnia nad Herzegovina.

Data of first authorisation / renewal of the authorisation in BIH :

NITRAX 40 mg prolonged release tablets

Date: 30.05.2018.

Number: 04-07.3-1-1816/14

NITRAX 60 mg prolonged release tablets

Date: 30.05.2018.

Number: 04-07.3-1-1817/14