

Nyzamac® SR 40 mg & 60 mg Capsules  
Isosorbide mononitrate

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Please 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 symptoms 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 on this leaflet. See section 4.

**What is in this leaflet:**

1. What Nyzamac SR Capsules are and what they are used for.
2. What you need to know before you take Nyzamac SR Capsules.
3. How to take Nyzamac SR Capsules.
4. Possible side effects.
5. How to store Nyzamac SR Capsules.
6. Contents of the pack and other information.

1. What Nyzamac SR Capsules are and what they are used for

The name of your medicine is Nyzamac SR Capsules. The active ingredient is isosorbide mononitrate. Nyzamac SR Capsules belong to a group of medicines called nitrates.

They are called prolonged-release capsules because they are manufactured in a way that allows the isosorbide mononitrate to be released and slowly absorbed by your body over a period of several hours.

Nyzamac SR Capsules are used in adults to prevent angina (chest pain) and work by opening up blood vessels and reducing the pain.

2. What you need to know before you take Nyzamac SR Capsules

**Do not take Nyzamac SR Capsules if you:**

- are under 18 years of age;
- are allergic to isosorbide mononitrate or any other medicines known as nitrates (glyceryl trinitrate, isosorbide dinitrate), or any of the other ingredients of Nyzamac SR Capsules listed in section 6 (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing);
- have any inflammation of the heart such as pericarditis;
- have been diagnosed with any of the following heart conditions
  - Low cardiac filling pressure,
  - Cardiac tamponade,
  - Hypertrophic obstructive cardiomyopathy;
- have had any serious damage to your heart, such as cardiomyopathy or have narrow heart valves;
- suffer from severe anaemia (low levels of red blood cells in the blood);
- have a low volume of blood in your body (hypovolaemia);
- have a head injury or bleeding of the brain;
- have closed-angle glaucoma (high pressure in the eyes);
- have low blood pressure (hypotension);
- have decreased blood supply to the brain (cerebrovascular insufficiency);
- are taking a medicine called Viagra (sildenafil) used for male erectile dysfunction.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Nyzamac SR Capsules if you:

- have recently had a heart attack;
- have an underactive thyroid gland (hypothyroidism);
- have angina due to other causes (such as a large heart muscle), or have an increased circulatory volume;
- have a head injury or bleeding of the brain;
- develop low blood pressure (hypotension), a slow heart rate (bradycardia), or worsening your angina;

- are at risk of having a stroke;
- have liver or kidney problems, especially if you are elderly;
- have cirrhosis of the liver;
- have a poor diet;
- have poor circulation;
- have consumed alcohol as this may lead to low blood pressure (hypotension);
- feel that you are developing a tolerance to Nyzamac SR Capsules;
- have a very low body temperature (hypothermia).

If you have an attack of angina whilst taking Nyzamac SR Capsules, do not stop taking your Nyzamac SR Capsules. Your doctor will provide another medicine to treat your condition.

**Children**

Nyzamac SR Capsules are not suitable for use in children.

**Other medicines and Nyzamac SR Capsules**

Tell your doctor or pharmacist if you are taking or have recently taken, or might take any other medicines, including medicines obtained without a prescription.

- It is especially important to tell your doctor if you are taking:
- medicines used to treat high blood pressure (e.g. propranolol, furosemide);
  - medicines used to treat heart failure (e.g. nifedipine, ramipril);
  - medicines used in the treatment of erectile dysfunction (e.g. sildenafil);
  - any medication which may cause a lowering of your blood pressure (e.g. causing dizziness or light-headedness, especially on standing);
  - medicines such as noradrenaline, which are used to treat high blood pressure or a heart attack;
  - acetylcholine, which is used during some operations;
  - medicines such as histamine, which is used to treat allergic reactions;
  - medicines used to treat migraines (e.g. ergotamine).

**Nyzamac SR Capsules with food, drink and alcohol**

Do not take Nyzamac SR Capsules at the same time as an alcoholic drink.

**Pregnancy and breast-feeding**

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. The safety of Nyzamac SR Capsules during pregnancy or whilst breast-feeding has not been established.

**Driving and using machines**

You can drive while taking Nyzamac SR Capsules but do not drive until you know how the capsules affect you. They may give you low blood pressure or make you feel dizzy, if they affect you in this way, **do not** drive or operate any machinery.

**Nyzamac SR Capsules contain lactose, sucrose and sodium.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Nyzamac SR Capsules

Always take Nyzamac SR Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose for adults is 40mg or 60mg a day, taken in the morning. Your doctor may increase this dose to 120mg, to be taken as a single dose.

You can take your medicine with or without food.

Please read the back of this leaflet

A lower dose may be prescribed for the first 2-4 days. The capsules should be **swallowed** whole with a glass of water. Do not crush or chew the capsules.

If Nyzamac SR Capsules are taken frequently and for long periods the effectiveness of the drug may decrease. If you notice that your capsules are no longer working as well at relieving the pain as they have done before, consult your doctor.

If you are elderly and suffer from low blood pressure, liver or kidney disease, your doctor may prescribe a lower dose for you to take.

**Use in children**  
Nyzamac SR Capsules are NOT recommended for children under 18 years of age.

**If you take more Nyzamac SR Capsules than you should**  
If you take more Nyzamac SR Capsules than you should, contact your doctor or nearest hospital emergency department immediately. Take this leaflet and any remaining capsules with you.

Symptoms of overdose include headache, feeling over-excited, flushing, cold perspiration, feeling sick, being sick, feeling dizzy, fainting, a fast heart beat, low blood pressure, confusion, shortness of breath and unconsciousness.

**If you forget to take Nyzamac SR Capsules**  
If you remember within 8 hours take the forgotten dose immediately.  
If you remember after 8 hours take the dose at the usual time.

**If you stop taking Nyzamac SR Capsules**  
Ask your doctor before stopping treatment with Nyzamac SR Capsules, as treatment should be reduced gradually over several days and you must be monitored carefully by your doctor.

4.Possible side effects

Like all medicines, Nyzamac SR Capsules can cause side effects, although not everyone gets them.

**If you experience the following side effects, you should STOP taking your medicine and tell your doctor IMMEDIATELY or go to your nearest casualty department.**

- skin troubles such as rash or itching;
- wheezing or shortness of breath.

These may be signs of an allergic reaction.

**Very Common (may affect more than 1 in 10 people):**

- headache, which may be throbbing - this usually becomes less after a few days of treatment.

**Common (may affect up to 1 in 10 people):**

- dizziness;
- lowered blood pressure (feeling light-headed, dizzy and a speeding up of the heart rate when standing up.
- Also feeling of weakness, drowsiness or increased heart rate).

**Uncommon (may affect up to 1 in 100 people):**

- nausea, vomiting;
- flushing;
- skin rashes;
- heartburn;
- paleness, sweating and restlessness - if your blood pressure drops severely, leading to passing out (collapse). Worsening of angina symptoms can occur if blood pressure drops severely.

**Rare (may affect up to 1 in 1,000 people):**

- increase in your heart rate (tachycardia).
- decrease in your heart rate (paroxysmal bradycardia).

These symptoms generally disappear during long-term treatment.

**Not known (frequency cannot be estimated from the available data):**

- muscle pain;
- weakness;
- inadequate supply of oxygen in the body (hypoxia);
- restlessness;
- sleepiness;
- pituitary haemorrhage;
- itching and allergic dermatitis;
- skin peeling;
- diarrhoea.

**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. You can also report side effects directly via the Yellow Card Scheme, website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

If Nyzamac SR Capsules are taken frequently and for long periods the effectiveness of the drug may decrease. If you notice that your capsules are no longer working as well at relieving the pain as they have done before, consult your doctor.

5.How to store Nyzamac SR Capsules

Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original package.

**KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.**

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 Nyzamac SR Capsules contain**  
The active ingredient is isosorbide mononitrate. Each 40mg prolonged-release capsule contains 40 mg of isosorbide mononitrate. Each 60mg prolonged-release capsule contains 60 mg of isosorbide mononitrate.

The other ingredients are: lactose monohydrate, sugar spheres (containing sucrose and maize starch), bleached dewaxed shellac, dewaxed shellac, talc, copolymer of methacrylic acid and methyl methacrylate (1:1) and copolymer of ethyl acrylate, methyl methacrylate and trimethylammonioethyl methacrylate chloride (1:2:0:1) and the capsule shells are made of gelatin and also contain the colouring titanium dioxide (E171).  
The black printing ink contains shellac, propylene glycol, ammonium hydroxide, potassium hydroxide and black iron oxide (E172).

**What Nyzamac SR Capsules look like and contents of the pack**  
The 40mg capsule is a size 2 capsules and has an opaque white cap printed with "ISMN SR" in black ink and an opaque white body printed with "40" in black ink, containing off-white to yellowish microgranules.  
The 60mg capsule is a size 1 capsule and has an opaque white cap printed with "ISMN SR" in black ink and an opaque white body printed with "60" in black ink, containing off-white to yellowish microgranules.

They are packaged in blister packs of 28, 30, 56 or 60 capsules.  
Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**  
Ethypharm  
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**For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder: United Kingdom: Ethypharm UK Ltd**  
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