

PACKAGE LEAFLET: INFORMATION FOR THE USER

MONIZOL

40 mg Tablets

ISOSORBIDE MONONITRATE

• 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 MONIZOL is and what it is used for
2. Before you take MONIZOL
3. How to take MONIZOL
4. Possible side effects
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1. WHAT MONIZOL IS AND WHAT IS IT USED FOR

Monizol Tablets belong to a group of medicines called organic nitrates. Organic nitrates work by widening the blood vessels in your heart to allow an increased amount of blood to flow to areas which need it.

Monizol Tablets are used to prevent angina pectoris.

Angina usually feels like a tight pain in the chest, neck or arm area. The pain comes from the heart muscle and is a sign that part of it is not getting enough oxygen for the amount of work it is doing.

Monizol Tablets can also be used to treat congestive heart failure. Heart failure can happen when the heart muscle is not strong enough to pump the blood around the body. It may cause problems with breathing and swelling of the legs.

2. BEFORE YOU TAKE MONIZOL

Do not take Monizol Tablets if:

- You are allergic to isosorbide mononitrate, other nitrates or any of the other ingredients of Monizol Tablets

- You suffer from severe anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- You have had a heart attack (myocardial infarction)
- You have had a brain haemorrhage (bleeding)
- You have had a head injury (trauma)
- You have severely low blood volume (hypovolaemia)
- You have severely low blood pressure
- Your blood has stopped circulating around your body properly (circulatory failure)
- You take sildenafil ("Viagra") or any other phosphodiesterase inhibitor.
- You are suffering from "shock" or vascular collapse
- You have an eye disease called glaucoma
- You have been diagnosed with any of the following heart conditions: hypertrophic obstructive cardiomyopathy (HOCM), constrictive pericarditis, cardiac tamponade, low cardiac filling pressures, aortic/mitral valve stenosis and diseases associated with raised intra-cranial (head) pressure.
- You take products that contain riociguat a medicine used in treating pulmonary hypertension.

If any of the above applies to you talk to your doctor or pharmacist.

Check with your doctor before taking Monizol Tablets if:

- You have an underactive thyroid gland
- You are malnourished (severely underfed)
- You have liver or kidney disease
- You suffer from hypothermia (a very low body temperature)
- You suffer from very poor circulation
- You have slower than normal bowel movements

Taking other Medicines

- Do not take Monizol Tablets with phosphodiesterase inhibitors such as Sildenafil ("Viagra") used for impotence. Using Monizol Tablets with these medicines could cause your blood pressure to fall to a dangerously low level. You must not stop taking Monizol Tablets to take Sildenafil as this will increase your chances of having an angina attack.
- Do not take Monizol Tablets with products that contain riociguat a medicine used in treating pulmonary hypertension.

Tell your doctor if you are taking any of the following medicines:

- Medicines to lower your blood pressure.
- Tricyclic antidepressants (used to treat depression) and neuroleptics (used to treat anxiety).
- Ergotamine used for migraine.
- Sapropterin used for phenylketonuria (PKU)
- Any other medicine, including medicines obtained without a prescription.

If any of the above applies to you, talk to your doctor.

Using Monizol Tablets with food and drink

Do not drink alcohol. It could increase the effect of Monizol Tablets and lower your blood pressure too much. If this happens, you may feel dizzy or faint.

Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking Monizol Tablets.

Your doctor will decide whether you should take this medicine.

Driving and using machines

Monizol Tablets may give you a headache, blurred vision or make you feel dizzy or tired. If this happens to you, do not drive or operate machinery.

Warnings about the ingredients in Monizol Tablets

This medicine contains lactose. If you have an intolerance to some sugars, tell your doctor before taking this medicine.

3. HOW TO TAKE MONIZOL

Always take Monizol Tablets exactly as your doctor has told you.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Adults

- The usual adult dose is one tablet two or three times a day
- Your doctor will tell you when you should take your tablets. You will need to have a period of time (usually when you are sleeping) when no tablets are taken. This is called a “nitrate low” period and is needed to make sure your medicine remains effective
- Swallow the tablets whole with a drink of water
- Your doctor may increase your dose, up to a maximum of 120 mg per day.

Do not use Monizol Tablets to treat an actual angina attack. Your doctor will give you a different medicine such as a GTN (glyceryl trinitrate) spray or tablet for this.

Children

This medicine is not suitable for children.

If you take more Monizol Tablets than you should

Do not take more Monizol Tablets than you should. If you accidentally take too much, immediately contact the nearest hospital casualty department or your doctor.

Too many Monizol Tablets may cause your blood pressure to fall too low, making you feel sick, faint and dizzy.

A very large overdose could cause a coma or collapse and require immediate resuscitation.

If you forget to take Monizol Tablets

Do not take a double dose to make up for a missed dose. Take your next dose at the usual time.

If you stop taking Monizol Tablets

Do not stop taking Monizol Tablets without first talking to your doctor. You should keep taking your medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the tablets your condition may get worse.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines Monizol Tablets can cause side effects, although not everybody gets them.

Seek immediate medical help if you have any of the following symptoms:

- Fainting or collapse

Very common side effects (affects more than 1 in 10 people):

- Headaches

Common side effects (affects less than 1 in 10 people):

- Dizziness

- Sleepiness
- Feeling weak
- Fast heartbeat
- Lowering of blood pressure when standing up.

They may occur for the first few days of treatment or after your dosage has been increased.

Uncommon side effects (affects less than 1 in 100 people):

- Fainting or collapse
- Feeling sick or being sick
- Skin rashes
- Looking pale
- Flushing
- Excessive sweating
- Restlessness
- Increase in chest pain/angina.

Very rare side effects (affects less than 1 in 10,000 people):

- Heartburn

Other Side Effects:

- Red or scaly skin (exfoliate dermatitis)
- Low Blood pressure
- Swelling of the skin

You may also suffer with increase chest pain due to a lack of oxygen to the heart muscle and areas around the chest.

Reporting of side effects

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

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MONIZOL

Keep out of the reach and sight of children.

Do not use Monizol Tablets after the expiry date on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.