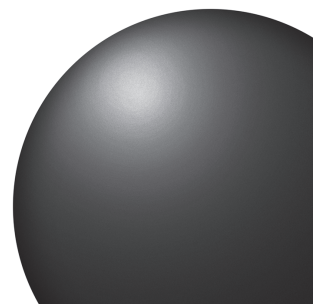


Package Leaflet: Information for the patient

Isosorbide Mononitrate

10 mg Tablets

CIA79268C 4020279 10/672 1695



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. 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 in this leaflet. See Section 4

What is in this leaflet:

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

1. What Isosorbide Mononitrate Tablets are and what they are used for

Isosorbide Mononitrate 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.

Isosorbide Mononitrate 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.

2. What you need to know before you take Isosorbide Mononitrate Tablets

Do not take Isosorbide Mononitrate Tablets if:

- You are allergic to isosorbide mononitrate, other nitrates or any of the other ingredients of Isosorbide Mononitrate Tablets (see section 6)
- 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 Isosorbide Mononitrate 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 Isosorbide Mononitrate Tablets with phosphodiesterase inhibitors such as Sildenafil (“Viagra”) used for impotence. Using Isosorbide Mononitrate Tablets with these medicines could cause your blood pressure to fall to a dangerously low level. You must not stop taking Isosorbide Mononitrate Tablets to take Sildenafil as this will increase your chances of having an angina attack.**
- **Do not take Isosorbide Mononitrate 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 Isosorbide Mononitrate Tablets with food and drink

Do not drink alcohol. It could increase the effect of Isosorbide Mononitrate 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 Isosorbide Mononitrate Tablets.

Your doctor will decide whether you should take this medicine.

Driving and using machines

Isosorbide Mononitrate 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 Isosorbide Mononitrate Tablets

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

3. How to take Isosorbide Mononitrate Tablets

Always take Isosorbide Mononitrate Tablets exactly as your doctor has told you. Check with your doctor if you are not sure.

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 Isosorbide Mononitrate 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 Isosorbide Mononitrate Tablets than you should

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

Too many Isosorbide Mononitrate 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 Isosorbide Mononitrate 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 Isosorbide Mononitrate Tablets

Do not stop taking Isosorbide Mononitrate 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 Isosorbide Mononitrate 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 (exfoliative 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 includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

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

5. How to store Isosorbide Mononitrate Tablets

Keep this medicine out of the reach and sight of children.

Do not use Isosorbide Mononitrate 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.

6. Contents of the pack and other information

What Isosorbide Mononitrate 10 mg Tablets contain

The active substance is isosorbide mononitrate 10 mg.

The other ingredients are lactose monohydrate, microcrystalline cellulose, potato starch, purified talc, colloidal silicon dioxide and aluminium stearate.

What Isosorbide Mononitrate 10 mg Tablets look like

Isosorbide Mononitrate 10 mg Tablets are white with "E/10" marked on them.

They come in blister packs of 14, 50, 56, 60, 84 and 90 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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If this leaflet is difficult to see or read or you would like it in a different format, please contact Merus Labs Luxco II S.à r.l. 26-28, rue Edward Steichen, L-2540 Luxembourg.



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