

Isosorbide Mononitrate Tablets 10mg Isosorbide Mononitrate Tablets 20mg Isosorbide Mononitrate Tablets 40mg

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

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

Isosorbide Mononitrate Tablets belong to a group of medicines called nitrate vasodilators. These work by relaxing the blood vessels of the heart, reducing the strain on the heart making it easier to pump blood. 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 (hypersensitive) to isosorbide mononitrate, isosorbide dinitrate or any of the other ingredients of Isosorbide Mononitrate Tablets (see section 6). An allergic reaction may include a rash, itching or difficulty breathing
- you have severe anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- you are having a heart attack (myocardial infarction)
- you have ever had a stroke
- you have a low blood volume (hypovolaemia), very low blood pressure
- your blood has stopped circulating around your body properly (circulation failure)
- you take sildenafil, tadalafil and vardenafil or any other phosphodiesterase inhibitor (used for male impotence). See the section "Other medicines and Isosorbide Mononitrate Tablets"
- you are also taking riociguat. See the section "Other medicines and Isosorbide Mononitrate Tablets"
- you are suffering from "shock" or vascular collapse
- you have an eye disease called glaucoma (increased pressure in the eye)
- 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
- you have diseases associated with raised head pressure e.g. brain haemorrhage (bleeding); head injury (trauma)

Do not take Isosorbide Mononitrate Tablets if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Isosorbide Mononitrate Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Isosorbide Mononitrate Tablets if you:

- have an underactive thyroid gland
- are undernourished as a result of a poor diet
- have severe liver or kidney problems
- suffer from hypothermia (very low body temperature)
- suffer from very poor circulation
- had any serious damage to your heart, such as a heart attack
- have an eye disease called glaucoma (increased pressure in the eye)

Do not take Isosorbide Mononitrate Tablets if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Isosorbide Mononitrate Tablets.

Other medicines and Isosorbide Mononitrate Tablets: Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Isosorbide Mononitrate Tablets can affect the way some medicines work and some medicines can have an effect on Isosorbide Mononitrate Tablets.

Do not take Isosorbide Mononitrate Tablets if you are taking the following medicines:

- **Sildenafil, tadalafil and vardenafil used to treat male erection dysfunction, should not be taken if taking nitrate preparations such as Isosorbide Mononitrate Tablets because a severe and possibly dangerous fall in blood pressure can occur. This would result in collapse, unconsciousness and could be fatal. You must not stop taking Isosorbide Mononitrate Tablets to take sildenafil, tadalafil or vardenafil as this will increase your chances of having an angina attack.**
- Riociguat since this can cause hypotension (abnormally low blood pressure)
- Noradrenalin (norepinephrine) to treat sharp and severe drop in blood pressure
- Acetylcholine used in some operations
- Medicines to treat high blood pressure such as ACE inhibitors, beta blockers, alpha blockers, angiotensin-II receptor agonists, clonidine, diazoxide, diuretics (water tablets), methyl dopa, moxonidine
- Histamine (used mostly as a diagnostic agent in some medical conditions)
- Tricyclic antidepressants (used to treat depression) and neuroleptics (used to treat anxiety)
- Dihydroergotamine used for migraine

Do not take Isosorbide Mononitrate Tablets if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Isosorbide Mononitrate Tablets.

Isosorbide Mononitrate Tablets and alcohol: 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, breast-feeding and fertility: 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: Isosorbide Mononitrate Tablets may give you headache, blurred vision or make you feel dizzy or tired, make sure you are not affected before you drive or operate machinery.

Isosorbide Mononitrate Tablets contains lactose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Isosorbide Mononitrate Tablets

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

Taking this medicine

- Take the tablets with a drink of water.
- Isosorbide Mononitrate Tablets 20 mg and 40 mg can be divided into equal doses.

How much to take

Adults

- The initial dose recommended, for patients not already accustomed to nitrate therapy to prevent angina pectoris, is one tablet twice a day.
- The usual adult dose is 20 mg tablet two or three times a day, then a maintenance dose of between 20-120 mg a day.
- 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.

You must not take Isosorbide Mononitrate Tablets for a sudden attack of angina. If you have a sudden attack, take a glyceryl trinitrate tablet (follow the instructions given on the label).

Patients with kidney or liver disease: A lower dose may be given.

Elderly: Dose should be reduced especially in patients with kidney or liver disease.

Children: Do not give these tablets to children.

If you take more Isosorbide Mononitrate Tablets than you should: If you take more Isosorbide Mononitrate tablets than you should, take to a doctor or go to a hospital straight away. Take the medicine pack with you so the tablets can be identified.

Signs of an overdose: pulsing headache, over excited, flushing, feeling or being sick, cold sweats, sweating, feeling dizzy or spinning sensation, restlessness, warm flushed skin, blurred vision fainting or passing out, fast heart beat or fall in blood pressure. Increase pressure in the brain with confusion and neurological deficits can sometimes occur. Methaemoglobinaemia, which manifests in symptoms such as bluish discoloration of the skin and mucous membranes (cyanosis); respiratory depression; seizures; irregular heart rate or rhythm.

If you forget to take Isosorbide Mononitrate Tablets

- If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

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 on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may happen with this medicine:

- Headaches
- Feeling sick (nausea)
- Feeling dizzy

The above problems usually disappear with time.

Other possible side effects:

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

- Fainting or collapse
- Allergic reaction- skin rash, swelling of the skin of the extremities or face, swelling of lips, tongue or the mucous membranes in mouth, throat or airways resulting in shortness of breath or difficulty to swallow

Very common side effects (may affect up to 1 in 10 people):

- Mild headaches at the start of treatment. Usually they get better after 1-3 weeks of treatment.

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

- Low blood pressure and/or light-headed on standing up
- Headache
- Dizziness
- Tiredness, drowsiness, feeling weak
- Fast or slow heart rate
- Flushing

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

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

- Fainting or collapse
- Feeling sick or being sick (nausea and/or vomiting), diarrhoea
- Skin rashes, looking pale
- Excessive sweating
- Restlessness
- Worse angina

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

- Fainting
- Rash
- Itchy skin

Very rare side effects (may affect up to 1 in 10,000 people):

- Heartburn
- Red or scaly skin (exfoliative dermatitis)
- Muscular pain (myalgia)

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 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.

5. How to store Isosorbide Mononitrate Tablets

- Keep this medicine 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.
- Store in a dry place, below 25°C.
- Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Content of the pack and further information

What Isosorbide Mononitrate Tablets contain: The active substance is isosorbide mononitrate. Each tablet contains either 10mg, 20mg or 40mg of the active substance. The other ingredients are lactose monohydrate, compressible sugar, sodium starch glycollate, magnesium stearate and colloidal silicon dioxide.

What Isosorbide Mononitrate Tablets look like and content of the pack

Isosorbide Mononitrate Tablets 10mg are white round tablets with an embossment "IM 10" on one side.

Isosorbide Mononitrate Tablets 20mg/40mg are white round tablets, scored on one side with an embossment

"ISMN 20"/"ISMN40".

Pack sizes are 28, 50, 56, 60, 100 or 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Dexcel® - Pharma Ltd., 2nd Floor, Bourn, 1 Manor House Drive, Coventry, CV1 2FX, UK

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