

PACKAGE LEAFLET: INFORMATION FOR THE USER

Isosorbide mononitrate 20 mg Tablets

Isosorbide mononitrate 40 mg Tablets

Isosorbide mononitrate

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, tell 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 is and what it is used for
2. What you need to know before you take Isosorbide mononitrate
3. How to take Isosorbide mononitrate
4. Possible side effects
5. How to store Isosorbide mononitrate
6. Contents of the pack and other information

1. What isosorbide mononitrate is and what it is used for

Isosorbide mononitrate belongs 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 is 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

Do not take Isosorbide mononitrate

- if you are allergic to the isosorbide mononitrate or to any of the other ingredients of this medicine (listed in section 6).
- if you suffer from severe disorders of the heart muscle or the pericardium causing severe impairment of the heart function is severely impaired (called constrictive pericarditis, pericardial tamponade or restrictive cardiomyopathy); 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.
- if you are simultaneously being treated with phosphodiesterase inhibitor (eg sildenafil, tadalafil and vardenafil medicines to treat erectile dysfunction and/or pulmonary hypertension
- if you suffer from severe low blood pressure (hypotension);
- if you suffer from severely impaired blood flow in the brain (cerebrovascular insufficiency).
- if you suffer from severe anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- if you have had a heart attack (myocardial infarction)
- if you have had a brain haemorrhage (bleeding)
- if you have had a head injury (trauma)
- if you have a low blood volume (hypovolaemia)

- if your blood has stopped circulating around your body properly (circulatory failure)
- if you are suffering from “shock” as the blood has stopped circulating properly around your body (circulatory failure) or vascular collapse
- if you have an eye disease called glaucoma
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Warnings and precautions

Talk to your doctor or pharmacist or nurse

before using isosorbide mononitrate. Take special care with isosorbide mononitrate

- if you are sensitive to the effects of **low blood pressure**; Isosorbide mononitrate should not be used, for example, by patients with **existing low blood pressure, shock, reduced thyroid function (hypothyroidism), anaemia, cerebral perfusion disorders or elevated intracranial pressure, patients who faint as a result of reduced perfusion (vascular collapse)**;
- if You have **an underactive thyroid gland**
- if You are **malnourished (severely underfed)**
- if You have **liver or kidney disease**
- if You suffer from **hypothermia (a very low body temperature)**
- if You suffer from **very poor circulation**

Tell your doctor if one of the above warnings applies to you, or has done so in the past. Isosorbide mononitrate is not intended for the treatment of sudden attacks of heart muscle spasm (angina pectoris).

Other medicines and isosorbide mononitrate

Tell your doctor

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

The following remarks may also be applicable to the use of medicines some time previously or in the near future. Isosorbide mononitrate may cause interactions with certain medicines. This means that each can influence the effect(s) or side effect(s) of the other. An interaction may occur when using this medicine with other drugs including:

- **Phosphodiesterase-5-inhibitors such as sildenafil, Alprostadil, Tadalafil and Vardenafil used for impotence (for the treatment of erectile dysfunction or high blood pressure in the blood vessels of the lungs) You must not use these medicines if you are receiving treatment with Isosorbide mononitrate. The antihypertensive effect is strengthened. This can result in life-threatening side effects, such as heart attacks;**
- other medicines with an antihypertensive effect which are often used in the treatment of high blood pressure, such as beta blockers (**atenolol, propranolol**), calcium channel blockers (**nifedipine, diltiazem**), vasodilators (**glycerol trinitrate, methyldopa**), angiotensin receptor blockers (**olmesartan medoxomil, candesartan cilexetil**)
- Tricyclic antidepressants (used to treat depression) such as **amitriptyline, clomipramine**, and neuroleptics to treat psychosis (delusions, hallucinations and/or disordered thought) such as phenothiazines (**fluphenazine**) or **butyrophenones (haloperidol)**
- dihydroergotamine (a drug to treat migraine). The hypertensive effect of this drug may be strengthened
- **Sapropterine** containing medicines for the treatment of hyperphenylalaninaemia (HPA)
- **aldesleukin** (a drug to treat metastatic cancer of the kidney).
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In this section, medicines are referred to by the name of the active substance or the group to which the substance belongs. You will often know a drug by its brand name. Therefore you should look on the

packaging or in the package leaflet of any medicine you are using in order to find out what substances it contains, or ask your doctor or pharmacist for advice.

Taking Isosorbide mononitrate with food and drink

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

Pregnancy and breast-feeding and fertility

If you are pregnant, trying to become pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking Isosorbide mononitrate. Your doctor will decide whether you should take this medicine.

Data on the use of isosorbide mononitrate in pregnancy are insufficient to be able to assess the possible harmful effect. Therefore you should avoid to use Isosorbide mononitrate during pregnancy. Data on the use of isosorbide mononitrate while breast-feeding are insufficient to be able to assess the possible harmful effect. As precautionary measure you should not use Isosorbide mononitrate during the period that you are breast-feeding.

Driving and using machines

Because isosorbide mononitrate causes a drop in blood pressure, dizziness can occur, especially at the start of treatment or if the dose is increased. Isosorbide mononitrate may also give you a headache, blurred vision or make you feel tired. If this happens do not drive any vehicle, because the use of Isosorbide mononitrate may lead to inability to drive safely. Nor must you use any tools and/or machines in this case.

Important information about some of the ingredients of Isosorbide mononitrate

This medicine 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

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

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 dose of Isosorbide mononitrate is 1 tablet of Isosorbide mononitrate 20 mg, 2 to 3 times daily. If dosage is not sufficient to get desirable effect, the dose may be increased to 1 tablet of Isosorbide mononitrate 40 mg, 2 to 3 times daily.

To prevent possible initial undesirable effect, the treatment should be started with possible lowest dose and slowly increased to the required dose.

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

The maximum dose is 120 mg per day.

To prevent tolerance, it is recommended that the dosage be kept as low as possible and that a sufficiently long nitrate-free interval is ensured to restore sensitivity (first dose in the morning and last dose late in the afternoon, e.g. at 8 am and 15 pm).

The tablet is swallowed whole with sufficient liquid to take. (e.g. 1 glass of water) after meals. The duration of application is decided by the treating physician.

Treatment with isosorbide mononitrate must not be stopped suddenly. Both the dosage and frequency of intake should be tapered off slowly

If you do not take the dose as prescribed by your doctor, you may develop a tolerance to Isosorbide mononitrate.

Do not use Isosorbide mononitrate 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.

The elderly

There are no dose adjustment is necessary.

Children

There is no experience with the use of isosorbide mononitrate in children. Therefore isosorbide mononitrate should not be given to children

If you take more Isosorbide mononitrate than you should

Too much Isosorbide mononitrate 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 have taken more Isosorbide mononitrate than you should, contact your doctor or pharmacist immediately. Take the medicine carton with you. Your doctor or pharmacist will then know exactly what you have taken.

If you forget to take Isosorbide mononitrate

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

If you stop using Isosorbide mononitrate

Carry on using your medicine until your doctor says you can stop. Do not stop using it just because you feel better. If you stop using the tablets, your condition may get worse. This medicine must be taken regularly. It does not work if you take it only when you suffer symptoms.

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

4. Possible side effects

Like all medicines, Isosorbide mononitrate can cause side effects, although not everybody gets them. The most side effects are dose-dependent and very common side effect is headache which occurs in approximately 25% of patients at the beginning of treatment. The headache usually disappears within about a week.

Seek immediate help if you are having an allergic reaction. This includes any of the following symptoms:

- Difficulty in breathing
- Swelling of your eyelids, face or lips
- Rash or itching especially those covering your whole body
- Collapse

- Fainting
- Exfoliative dermatitis (serious illness with blistering of the skin, mouth, eyes and genitals)

If you experience any symptoms of shock or collapse after first dose, please contact your doctor immediately.

The following side effects have been reported:

very common (may affect more than 1 user in 10 people):

- headache

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

- dizziness (including dizziness on standing up)
- drowsiness
- sleepiness
- feeling weak
- tiredness
- low blood pressure
- increased heartbeat

uncommon (may affect up to 1 in 100 people):

- worsening agina (tight pain in the chest, neck or arm area)
- vomiting
- diarrhoea

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

- fainting
- skin rashes
- itching

very rare (may affect up to 1 in 10,000 people):

- upset stomach or indigestion

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

- excessive sweating,
- allergic skin reaction & flushing

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

Very slow heart rate has been reported with use of nitrates.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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

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

Store below 30°C.
Store in the original package.

Do not use Isosorbide mononitrate after the expiry date which is stated on the carton and the blister strip after EXP. The expiry date refers to the last day of the 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 Isosorbide mononitrate contains

The active substance is isosorbide mononitrate
Each tablet contains [20 mg /40 mg] of isosorbide mononitrate.

The other ingredients are lactose monohydrate, microcrystalline cellulose (PH 102) (E460), sodium starch glycolate (type A), colloidal anhydrous silicon dioxide (E551) and magnesium stearate (E470b).

What Isosorbide mononitrate looks like and contents of the pack

Isosorbide mononitrate 20 mg tablets: White to off-white, round, flat, bevelled edge uncoated tablets, debossed with 'AS' on one side and break line on the other side. The tablets can be divided in to equal halves.

Isosorbide mononitrate 40 mg tablets: White to off-white, round, flat, bevelled edge uncoated tablets, debossed with 'AT' on one side and break line on the other side. The tablets can be divided in to equal halves.

Pack sizes: 20, 28, 30, 40, 50, 56, 60, 80, 84, 90, 100, 200 or 500 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Limited,
Sage House, 319, Pinner Road,
North Harrow, Middlesex,
HA1 4HF,
United Kingdom

Manufacturer:

Accord Healthcare Limited,
Sage House, 319, Pinner Road,
North Harrow, Middlesex,
HA1 4HF,
United Kingdom

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