

Isobide MR tablets

Isosorbide mononitrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Isobide MR.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Isobide MR against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Isobide MR is used for

Isobide MR is used to prevent angina pectoris (heart pain). It is not recommended and should not be taken for the treatment of acute attacks.

Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart. The pain of angina is usually brought on by exercise or stress.

Isobide MR belongs to a group of medicines called nitrates. It works by widening blood vessels to improve the blood flow around the heart which means there is more oxygen being carried by the blood.

This reduces the pain associated with angina.

Your doctor may have prescribed Isobide MR for another reason. Ask your doctor if you have any questions about why Isobide MR has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before You Take Isobide MR

When you must not take it

Do not take Isobide MR if:

- 1. you have an allergy to:**
 - isosorbide mononitrate or any of the ingredients in Isobide MR listed at the end of this leaflet

- any medicine or food containing nitrates or nitrites

Symptoms of an allergic reaction to these medicines may include

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting

- 2. you are taking any of the following phosphodiesterase type 5 inhibitors**

- Sildenafil
- Tadalafil
- Vardenafil

- 3. You are pregnant, or intend to become pregnant**

Isosorbide may affect your developing baby if you take it during pregnancy.

4. You are breast feeding or intend to breast feed

Isosorbide passes into breast milk. The effect on the baby is unknown.

The use of Isobide MR during pregnancy or breast feeding should be discussed with your doctor.

Isobide MR should not be taken to stop an acute angina attack. They should be taken once daily.

Do not take Isobide MR if you are in a state of shock including shock caused by very low blood pressure due to a failing heart, have hypotension (low blood pressure), weakened muscle of the heart or pericarditis (swelling around the heart).

Do not take this medicine if the packaging is torn or shows signs of tampering.

Do not take if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking Isobide MR, contact your doctor.

Do not give Isosorbide to a child.

The safety and effectiveness of Isosorbide has not been established in children.

Before you start to take it

Tell your doctor if:

- 1. You have any allergies to any other medicines, foods, dyes or preservatives.**

2. You have or have had any medical conditions, especially the following:

- Heart failure
- Liver failure
- Kidney failure

3. You know you suffer from hypotension (low blood pressure) or blood vessel disease such as hardening of the arteries.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Isobide MR and may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

The combination of Isosorbide with Sildenafil (Viagra®), Tadalafil and Vardenafil may cause fainting or heart attacks.

The combination of N-acetylcysteine or captopril with Isosorbide may result in a prolonged anti-angina effect.

The combination of Isosorbide with a calcium channel blocker of the verapamil type may improve heart function. However, the combination of Isosorbide with any other calcium channel blocker may cause hypotension (low blood pressure) requiring dose adjustment of either medicine.

The combination of Isosorbide with betablocker medicines such as propranolol may cause hypotension (low blood pressure).

Be careful when drinking alcohol while you are using Isosorbide. If you drink alcohol, your blood pressure may drop, making you feel dizzy or faint.

Your doctor and pharmacist may have more information on

medicines to be careful with or avoid while taking Isobide MR.

How to take Isobide MR

How much to take

Your doctor will advise you on how many tablets you should take.

How to take it.

Take Isobide MR with half a glass of water. You must swallow the tablet whole.

Food does not affect the absorption of isosorbide so the tablets may be taken with or without food.

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the packaging, ask your doctor or pharmacist for help.

If you forget to take it

If you miss a dose of Isobide MR, take it as soon as you remember unless more than eight hours have passed.

If more than eight hours have passed since the time the dose should have been taken, do not take the missed dose but take the next dose at the normal time.

A missed dose may lead to an angina attack that in turn may need medication, prescribed by your doctor, capable of treating an acute attack such as use of immediate release tablets or spray administered under the tongue. Isobide MR is not recommended and should not be taken for the treatment of acute angina attacks.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Isobide MR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Isobide MR, the most common symptom is a pulsing headache. More serious symptoms are excitation, flushing, cold sweats, nausea, vomiting, vertigo, increased heart beat and a fall in blood pressure.

While you are taking Isobide MR

Things you must do

Use Isobide MR exactly as your doctor has prescribed.

If you do not follow your doctor's instructions, you may not get relief from your attacks of angina.

Tell your doctor if you continue to have angina attacks or if they become more frequent while you are using Isobide MR.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Isobide MR.

Things you must not do

Do not use it to treat any other complaints unless your doctor says to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful driving or operating machinery until you know how Isobide MR affects you.

Isobide MR may cause tiredness, dizziness or lightheadedness in some people, especially after the first dose. Make sure you know how you react to Isobide MR before you drive a car, operate machinery or do anything else that could be dangerous.

Be careful not to overdo physical activities when you first start using Isobide MR.

You may feel better when you start taking it, but you will need time to improve your physical fitness.

Get up slowly when getting out of bed or standing up if you feel light-headed, dizzy or faint.

You may feel light-headed or dizzy when you begin to take Isosorbide or if the dose is increased. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. The problem usually goes away after the first few days.

If this problem gets worse or continues, talk to your doctor.

Be careful when drinking alcohol while you are using Isobide MR.

If you drink alcohol while using Isobide MR, your blood pressure may drop, making you feel dizzy or faint.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Isobide MR.

Isobide MR helps most people with angina, but it may have unwanted effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of

the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

Isobide MR often causes adverse effects in the early stages of treatment.

More common reactions

Headache is the main adverse reaction which is quite common when you start taking Isobide MR. The incidence of headaches usually reduces as treatment is continued. Other symptoms such as dizziness, nausea, tiredness, and disturbed sleep may also occur. Again, these side effects reduce over time if Isobide MR is continued.

Less common reactions

Other side effects which have been reported are poor appetite, vomiting, diarrhoea and heartburn.

These may be serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Some people may experience other side effects while taking Isobide MR.

These side effects are not listed above. Tell your doctor if you notice anything else that is making you feel unwell.

After taking Isobide MR

Storage

Keep Isobide MR where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in the packaging until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place.

Isobide MR should be stored below 25 degrees C.

Do not store Isobide MR or any other medicine in the bathroom or near a sink.

Do not leave in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Isobide MR, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Isobide MR 60 mg tablets are oval tablets with a cream coloured film coating and half scored on both sides.

They are presented in blister (AUST R 184066) or bottle (AUST R 184067)* packs of 30 tablets.

*not marketed

Ingredients

Active Ingredient:

Isobide MR tablets contain 60 mg isosorbide mononitrate.

Other Ingredients:

Also contains stearic acid, carnauba wax, hypromellose, lactose monohydrate, magnesium stearate, purified talc, titanium dioxide, colloidal anhydrous silica, macrogol 4000, iron oxide yellow.

Please read this leaflet carefully before you start taking Isobide MR. You may wish to keep it to read again.

Name and Address of the Sponsor

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