

GenRx Isosorbide Mononitrate Tablets

Contains the active ingredient, isosorbide mononitrate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some of the common questions people ask about Isosorbide Mononitrate Sustained-Release tablets.

It does not contain all the information that is known about isosorbide mononitrate.

It does not take place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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

Keep this leaflet with the medicine. You may need to read it again.

What this medicine is used for

The name of your medicine is GenRx Isosorbide Mononitrate Sustained-Release tablets. It is used to prevent angina.

Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or the neck and sometimes to the shoulders and back. This is caused by too little blood and oxygen getting to the heart.

The pain of angina is usually brought on by exercise or stress.

How it works

Isosorbide mononitrate belongs to a group of medicines called nitrates. It works by relaxing the blood vessels, letting more blood and oxygen reach the heart.

It is not recommended that isosorbide mononitrate be taken for the treatment of acute attacks.

Your doctor will have explained why you are being treated with isosorbide mononitrate and told you what dose to take.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

However, your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Isosorbide mononitrate is not addictive.

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

Use in children

There is not enough information to recommend the use of this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you are allergic to it or food containing nitrates, nitrites or any ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

Do not take this medicine if you are intolerant or allergic to lactose.

GenRx Isosorbide Mononitrate tablets contain lactose.

Do not take isosorbide mononitrate if you have the following medical conditions:

- extremely low blood pressure
- shock including those caused by low blood pressure or failing heart
- pericarditis (swelling around the heart)
- weakened muscle of the heart.

You must not use isosorbide mononitrate whilst taking sildenafil (Viagra®), vardenafil (Levitra®), tadalafil (Cialis®).

Do not take isosorbide mononitrate tablets if you are pregnant or breast-feeding unless your doctor says it is safe. Ask your doctor about the risks and benefits involved.

It is not known whether it is safe to take isosorbide mononitrate whilst you are pregnant. It may affect your baby.

It is not known if your baby can take in isosorbide mononitrate from breast milk if you are breast-feeding.

Do not give this medicine to children.

There is no specific information about the use in children, so isosorbide mononitrate is not recommended for use in children. Always ask your doctor before giving medicines to children.

Do not use after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if:

1. you have any allergies to:
 - any medicine, foods, preservatives or dyes
 - lactoseIf you have an allergic reaction you may get a skin rash, hayfever, asthma or feel faint.
2. you have any of these medical conditions:
 - any illness affecting your liver or kidneys
 - low blood pressure (this can make you feel faint, weak or dizzy, especially if you stand up suddenly)
 - heart and blood vessel problems.It may not be safe for you to take isosorbide mononitrate tablets if you have any of these conditions.

Do not use this medicine to treat acute angina.

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- medicines used to treat impotence in men e.g. sildenafil (Viagra®), vardenafil (Levitra®), tadalafil (Cialis®)
- medicines that you buy without a prescription from a pharmacy, supermarket or health food shop
- medicines used to treat high blood pressure and heart conditions, such as calcium antagonists
- medicines used to treat liver disease, namely propranolol.

These medicines may affect the way isosorbide mononitrate works.

Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

If you have not told your doctor any of these things, tell them before you take any isosorbide mononitrate tablets.

How to take this medicine

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

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

How to take it

Take one tablet at about the same time each day.

If your doctor tells you to take two tablets each day, take both tablets at the same time.

Taking the tablets at 24 hour intervals makes sure they keep working properly.

Swallow the tablets whole, with half a glass of water or other liquid e.g. fruit juice, milk. Do not halve, chew or crush the tablets.

GenRx Isosorbide Mononitrate Sustained-Release tablets are designed to let the drug out over a number of hours. If they are crushed or chewed they won't work properly.

The tablets are composed of a waxy substance that does not dissolve in the body. You may find the outer shell of the tablets in your bowel motions. The medication in them has already been absorbed by the body.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, as long as it is not more than 8 hours late.

If it is more than 8 hours after you should have taken your dose, wait until the right time the next day to take it.

Do not double the dose.

You may find that you will need to use the tablets or spray that your doctor has given you to use during angina attacks if you miss a dose.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

In case of overdose

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to casualty at your nearest hospital if you think you or anyone else may have taken too much isosorbide mononitrate.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much isosorbide mononitrate, you will have a pulsing headache. You may also feel excited, flushed, have cold sweats, nausea (feeling sick) and vomit.

While you are taking this medicine

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking isosorbide mononitrate.

Tell your doctor immediately if you become pregnant.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Take this medicine regularly once every day.

If you don't, you will be more likely to get attacks of angina.

Tell your doctor if you continue to get angina attacks, or they become more frequent, while you are taking isosorbide mononitrate.

Things you must not do

Do not take this medicine to relieve acute attacks of angina.

Your doctor will have given you other tablets or spray to use when you get attacks of angina.

Do not take medicines known as phosphodiesterase type 5 inhibitor used to treat impotence (or erectile dysfunction) whilst on this medicine.

Do not stop taking this medicine unless you have discussed it with your doctor.

Do not take this medicine for any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

You will probably feel better when you start taking this medicine, but be careful not to overdo physical activities straight away. You will need time to improve your physical fitness.

Be careful driving or operating machinery until you know how this medicine affects you. Isosorbide mononitrate may cause dizziness and fainting in some patients, especially when you first start to take it. Make sure you know how you feel when you are taking this medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

Be careful when drinking alcohol while you are using this medicine.

If you drink alcohol while you are taking this medicine, your blood pressure may drop, making you feel dizzy or faint.

Please take to your doctor or pharmacist about these possibilities if you think they may bother you.

Possible side effects

Isosorbide mononitrate helps most people with angina, but it may have unwanted side effects in a few people. All medicines may have some unwanted side effects.

Sometimes they are serious, most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Ask your doctor or pharmacist to answer any questions you may have.

Following is a list of possible side effects. DO not be alarmed by this list. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- dizziness, lightheadedness or feeling faint
- feeling sick (nausea)
- rapid heart beat
- poor appetite
- vomiting
- heartburn
- diarrhoea
- rash, itching
- tiredness or sleep disturbances
- muscle tenderness or weakness, not caused by exercise.

Headache is the most common side effect whilst taking isosorbide mononitrate tablets. It can occur at the beginning of treatment, but usually goes away after a few days.

These are all mild side effects of isosorbide mononitrate.

Other side effects not listed above may occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell.

Storage and disposal

Storage

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

If you take the tablets out of the blister pack, it will not keep well.

Keep it in a cool dry place, protected from light and where the temperature stays below 25°C.

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

Do not leave it in the car on hot days or near a windowsill.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that they have expired.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What GenRx Isosorbide mononitrate tablets look like

GenRx Isosorbide Mononitrate Sustained-Release 60 mg tablets are cream, film-coated oval tablets of 13mm length scored on both sides.

They are available in blister packs of 30 tablets.

Ingredients

Each GenRx Isosorbide Mononitrate tablet contains 60 mg of isosorbide mononitrate as the active ingredient.

They also contain the following inactive ingredients:

- stearic acid
- carnauba wax
- hypromellose
- lactose
- magnesium stearate
- talc
- titanium dioxide
- siliceous earth - purified
- macrogol 4000
- iron oxide yellow CI77492.

GenRx Isosorbide Mononitrate Sustained-Release tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

Australian Registration Numbers

GenRx Isosorbide Mononitrate 60 mg Sustained Release Tablets (blister pack): AUST R 75240.

Sponsor

Apotex Pty Ltd
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