

APO-Isosorbide Mononitrate Sustained-Release Tablets

Isosorbide mononitrate

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some of the common questions people ask about isosorbide mononitrate. It does not contain all the information that is known about this medicine. It does not take place of talking to your doctor or pharmacist.

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.

If you have any concerns about taking this medicine, ask your doctor or pharmacist

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

Isosorbide mononitrate sustained-release tablets are 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

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 have any allergy to:

- isosorbide mononitrate
- food containing nitrates
- nitrites

- any ingredients listed at the end of this leaflet.

Some of the 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 or joint pain, tenderness
- rash, itching or hives on the skin.

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

These tablets contain lactose.

Do not take isosorbide mononitrate if you have or have had any of the following medical conditions:

- extremely low blood pressure
- shock, including when caused by low blood pressure or heart failure
- 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 use this medicine to treat acute angina.

Do not take isosorbide mononitrate tablets if you are pregnant, plan to become pregnant or are breastfeeding.

It is not known whether it is safe to take isosorbide mononitrate whilst you are pregnant or breast-feeding. It may affect your baby. Ask your doctor about the risks and benefits involved.

Do not use after the 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

Tell your doctor if you have any allergies to any medicines, foods, preservatives or dyes.

Tell your doctor if you have any of the following medical conditions:

- liver or kidney problems
- low blood pressure
- heart and blood vessel problems

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines and isosorbide mononitrate may interfere with each other. These include:

- medicines used to treat male impotence e.g. (sildenafil, vardenafil, tadalafil)
- medicines used to treat high blood pressure and heart conditions (e.g. verapamil)
- medicines used to treat liver disease (e.g. propranolol)

These medicines may be affected by this medicine or may affect how well isosorbide mononitrate works. You may need different amounts of your

medicines, or you may need to take different medicines.

Your doctor or pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

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

They may differ to the information contained in this leaflet.

If you do not understand the instructions on the box, 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 you are taking any other medicines.

The usual dose is one tablet taken once a day. This may be increased by your doctor if necessary, to two tablets taken once a day.

How to take it

Swallow the tablets whole with water. Do not halve, chew or crush the tablets.

APO- Isosorbide mononitrate sustained-release tablets are designed to let the drug out over several 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.

When to take it

Take this medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also

help you to remember when to take it.

How long to take it for

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

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

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.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency 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.

Symptoms of an overdose include a pulsing headache, feeling excited, flushed, cold sweats, nausea or vomiting.

While you are taking this medicine

Things you must do

If you are started on any new medicines, remind your doctor and pharmacist that you are taking this one.

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

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

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 miss doses, 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 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.

Do not stop taking this medicine or change the dosage without checking with your doctor.

Things to be careful of

Speak to your doctor about starting any new physical activities while on this medicine.

You will probably feel better and more active when you start taking this medicine, but you may 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.

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.

Side effects

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

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. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- headache (usually goes away after a few days)
- dizziness, light-headedness or feeling faint

- stomach complaints, such as nausea, vomiting, heartburn, diarrhoea
- rapid heart beat
- poor appetite
- rash, itching
- tiredness or sleep disturbances
- muscle tenderness or weakness, not caused by exercise.

The above list includes the more common side effects of isosorbide mononitrate.

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

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

Storage and disposal

Storage

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

If you take the tablets out of the 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

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

Cream, film-coated oval tablets of 13mm length and half scored on both sides.

Available in blister packs of 30 tablets. AUST R 75240.

Ingredients

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

They also contain the following:

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

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

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This leaflet was prepared in December 2018.