

## ISOMONIT®

isosorbide mononitrate (i-SO-sor-bide mo-no-NI-trat) 60 mg tablet

### Consumer Medicine Information

#### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Isomonit.

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

All medicines have risks and benefits. Your doctor has weighed the risk of you taking Isomonit against the benefits it is expected to 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 want to read it again.

#### WHAT ISOMONIT IS USED FOR

The name of your medicine is Isomonit. It contains the active ingredient isosorbide mononitrate.

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

Your doctor may have prescribed Isomonit for another reason.

**Ask your doctor if you have any questions about why Isomonit was prescribed for you.**

#### How Isomonit works

Isomonit belongs to a group of medicines called nitrates. Isomonit reduces the amount of work the heart has to do. It does this by increasing the size of the blood vessels around the heart. This also improves the blood flow around the heart which means there is more oxygen being carried by the blood. This combination of actions reduces the pain associated with angina.

There is no evidence that Isomonit is addictive.

#### BEFORE YOU TAKE ISOMONIT

##### When you must not take Isomonit

##### Do not take Isomonit if:

- you are allergic to the active ingredient isosorbide mononitrate or any of the inactive ingredients mentioned at the end of this leaflet under PRODUCT DESCRIPTION; you are allergic to food containing nitrates or nitrites
- it is past its expiry date or the packaging appears to have been tampered with
- you are pregnant or breastfeeding, unless permitted by your doctor
- you are in a state of shock including shock caused by very low blood pressure due to a failing heart
- you have hypotension (low blood pressure)
- you have a weakened muscle of the heart or pericarditis (swelling around the heart)
- you are taking sildenafil (Viagra®), vardenafil (Levitra®), tadalafil (Cialis®).

Isomonit should not be taken to stop an acute angina attack. It should only be taken once daily.

##### Do not give Isomonit to children.

There is not specific information about use in children, so Isomonit is not recommended for use in children. Always ask your doctor before giving medicines to children.

##### Before you start to take Isomonit

##### Tell your doctor if you have allergies to:

- any other medicines, especially if they are in the same drug class as isosorbide mononitrate
- any other substances, including foods, preservatives or dyes.

The use of Isomonit during pregnancy or breastfeeding should be discussed with your doctor.

##### Tell your doctor if you have or have had any medical conditions, especially the following:

- treatment for any heart complaints at present
- any liver failure
- any kidney failure
- hypotension (low blood pressure)
- blood vessel disease (e.g. hardening of the arteries).

##### Taking other medicines

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

##### In particular, tell your doctor if you take any of the following:

- sildenafil (Viagra®), vardenafil (Levitra®), tadalafil (Cialis®)
- N-acetylcysteine
- captopril
- calcium channel blockers
- beta-blocker medicines.

The combination of Isomonit with sildenafil (Viagra®), vardenafil (Levitra®), tadalafil (Cialis®) may cause fainting or heart attacks.

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

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

The combination of Isomonit with beta-blocker medicines such as propranolol may cause hypotension (low blood pressure).

You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor will advise you.

#### HOW TO TAKE ISOMONIT

**Take Isomonit with half a glass of water. You must swallow the tablet whole.**

**Take ONE (1) tablet taken once a day. If your doctor tells you to take TWO (2) tablets daily, both tablets should be taken at the same time.**

Food does not affect the absorption of isosorbide mononitrate from Isomonit so that

the tablets may be taken with or without food.

It is important that Isomonit is only taken once daily. This is so that there are some hours of the day where there are low levels of drug in the blood. This reduces the risk of the body getting used to the drug which could mean it wouldn't work so well.

##### If you forget to take your dose

**If you miss a dose of Isomonit, take it as soon as you remember unless more than eight hours have passed. If more than eight hours have passed since the last dose was taken, do not take the missed dose but take the next dose at the normal time.**

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

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. Isomonit tablets are not recommended and should not be taken for the treatment of acute angina attacks.

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

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

##### If you take too much

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Isomonit.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

The most common symptom of overdose is a pulsing headache. More serious symptoms are excitation, flushing, cold sweats, nausea, vomiting, vertigo, increased heartbeat and a fall in blood pressure.

Induce vomiting if possible.

#### WHILE YOU ARE TAKING ISOMONIT

##### Things you must do

- **Always follow your doctor's instructions carefully.**
- **Tell your doctor if you become pregnant while taking Isomonit.**
- **If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Isomonit.**
- **Tell your doctor if you continue to get angina attacks, or they become more frequent while you are taking Isomonit.**

##### Things you must not do

- **Do not stop taking Isomonit without your doctor's permission. It is important not to stop taking this medicine abruptly.**
- **Do not use Isomonit to treat any other complaint unless your doctor says so.**

- **Do not give this medication to anyone else, even if their symptoms seem similar to yours.**
- **Do not take medicines known as phosphodiesterase type 5 inhibitor used to treat impotence (or erectile dysfunction) whilst on Isomonit.**
- **Do not take Isomonit to relieve acute attacks of angina.**  
Your doctor will have given you other tablets or a spray to use when you get attacks of angina.

#### *Things to be careful of*

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

Isomonit may cause tiredness or dizziness especially when you first start to take it. Make sure you know how you feel when you are taking Isomonit 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 Isomonit.**

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

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#### SIDE EFFECTS

All medicines can have 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 list of possible side effects. You may not experience any of them.**

Isomonit often causes adverse effects in the early stages of treatment.

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

- headache
- feeling faint
- dizziness
- fatigue
- muscle tenderness or weakness, not caused by exercise.

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

These are all mild side effects of Isomonit.

**Tell your doctor if you notice any other effects while taking this medicine.**

Other side effects not listed above may also occur in some people.

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#### AFTER TAKING ISOMONIT

##### *Storage*

**Keep Isomonit in the original packaging until you need to take it.**

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

**Store below 25°C in a dry place, out of the reach of children.**

**Protect from light and moisture.**

##### *Disposal*

**Return any unused or out of date medicine to your pharmacist.**

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#### PRODUCT DESCRIPTION

##### *What Isomonit looks like*

Isomonit 60 mg: cream coloured, scored tablets. They are available in packs of 30 tablets.

##### *Ingredients*

###### **Active Ingredient**

Isomonit tablets contain isosorbide mononitrate as the active ingredient.

###### **Inactive Ingredients**

As well as the active ingredient, Isomonit also contains some inactive ingredients. These are stearic acid, carnauba wax, hypromellose, lactose, magnesium stearate, talc, titanium dioxide, siliceous earth, macrogol 4000, iron oxide yellow CI77492.

##### *Supplier*

Sandoz Pty Ltd  
ABN 60 075 449 553  
54 Waterloo Road  
Macquarie Park, NSW 2113  
Australia

**Tel: 1800 634 500**

This leaflet was revised in February 2016.

###### **Australian Register Number**

Isomonit 60 mg sustained release tablets (blister): AUST R 75241.