

## 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

Isomonit 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.

Isomonit belong to a group of medicines called nitrates. It contains the active ingredient isosorbide mononitrate.

Isomonit work by relaxing the blood vessels, letting more blood and oxygen reach the heart.

Your doctor will have explained why you are being treated with Isomonit 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.

Isomonit is not 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 food containing nitrates or nitrites or any of the inactive ingredients mentioned at the end of this leaflet under Product Description
- you have hypotension (low blood pressure)
- you are in a state of shock including shock caused by very low blood pressure due to a failing heart
- you have a weakened muscle of the heart or pericarditis (swelling around the heart)
- you are taking sildenafil, vardenafil, tadalafil
- it is past its expiry date or the packaging appears to have been tampered with

**Do not use Isomonit if you are pregnant or breast feeding unless your doctor says it is safe. Ask your doctor about the risks and benefits involved.**

We do not know if it is safe for you to take it while you are pregnant. It may affect your baby.

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

**Do not give Isomonit to children.**

There is no specific information about use in children, so Isomonit 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 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.

If you have an allergic reaction you may get a skin rash, hayfever, asthma or feel faint.

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

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

- any illness affecting your liver or kidneys
- low blood pressure (this can make you feel faint, weak or dizzy, especially when you stand up suddenly)
- heart and blood vessel problems

It may not be safe for you to take Isomonit if you have any of these conditions.

**Do not use Isomonit to treat acute angina.**

**Isomonit must be taken once daily.**

**Do not stop taking it abruptly.**

*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.

These medicines may affect the way Isomonit work.

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

If you have not told your doctor about any of these things, tell them before you take any Isomonit.

#### 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.**

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

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. You may also feel excited, flushed, have cold sweats, nausea (feeling sick) and vomit.

#### 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.

**Be careful driving or operating machinery until you know how Isomonit affects you.**

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

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

This medicine helps most people with angina, but it may have unwanted side 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 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.**

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

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

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### *Storage*

**Keep Isomonit in the original packaging until it is time to take them.**

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.**

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

**Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it 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.

### *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 medicine that is left over.**

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## PRODUCT DESCRIPTION

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### *What Isomonit looks like*

Isomonit modified release tablets are oval tablets with a cream coloured film coating and half scored on both sides. 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 monohydrate, magnesium stearate, purified talc, titanium dioxide, purified 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 726 369**

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#### **Australian Register Number**

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