

ISOMONIT[®] 60 RETARD TABLET

Isosorbide-5-mononitrate (60mg)

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Read this entire leaflet before you start taking the medication.

- Keep this leaflet. You may need to read again.
- Ask your doctor or pharmacist if you need more information or advice.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

WHAT ISOMONIT IS USED FOR

Isomonit is used to:

1. Prevent angina pectoris (chest pain). It is not recommended and should not be taken for the treatment of acute attacks.
2. Treat congestive heart failure in combination with cardiac glycosides and/or diuretics.

Ask your doctor if you have any questions about why this medicine was prescribed for you. Your doctor may have prescribed it for another reason.

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.

BEFORE YOU USE ISOMONIT

When you must not use it

- You are allergic to the active ingredient isosorbide mononitrate, its related substance or any of the ingredients in this preparation
- You have low blood pressure
- You have a weakened muscle of the heart or swelling around the heart
- You are taking medication for erectile dysfunction such as sildenafil, vardenafil and tadalafil
- You suffer from glaucoma

Do not give this medicine to children.

Before you start to use it

- 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.

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

- Treatment for any heart complaints at present
- Any liver problems
- Any kidney problems
- Hypotension (low blood pressure)
- Blood vessel disease (e.g. hardening of blood vessels)

Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor will advise you. In particular, tell your doctor if you take any of the following:

- Medicines for erectile dysfunction (eg: sildenafil, vardenafil and tadalafil)
- N-acetylcysteine, medicines to break down phlegm.
- Methionine, a type of amino acid usually present in supplements
- Medicines for high blood pressure such as calcium channel blockers (eg: verapamil),

beta-blocker (eg. propranolol) and ACE-Inhibitor (eg. Captopril)

- Tricyclic antidepressants (eg. imipramine)
- Medicines for analgesic (pain-relieving) and antipyretic (fever-reducing) effects (e.g. Non-steroidal anti-inflammatory drugs and acetylsalicylic acid)
- Dihydroergotamine, medicines used to treat migraines.
- Alcohol

Pregnancy and lactation

Discuss the use of Isomonit during pregnancy or breast feeding with your doctor.

HOW TO USE ISOMONIT

Take your medication exactly as directed by your doctor.

How much to use

One Isomonit[®] 60 Retard Tablet to be taken once daily.

When to use it

Swallow whole with a glass of water in the morning or evening. Do not chew or crush the tablet.

How long to use it

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 very important that you do not stop taking this medicine suddenly.

If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed.

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

If you use too much (overdose)

If you or anyone else takes too many tablets, you tell your doctor and go to your nearest hospital emergency department immediately. Do this even if there are no signs of

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discomfort or poisoning. Take the carton or any remaining tablets you have with you.

Symptoms of an overdose may include pulsing headache, fever, nausea, vomiting etc.

WHILE YOU ARE USING IT

Things you must do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Isomonit[®] 60 Retard Tablet.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.
- Always follow your doctor's instructions carefully.
- Inform your doctor immediately if you are pregnant while taking Isomonit.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.
- Tell your doctor if you continue to experience angina attack or if it becomes more frequent.

Things you must not do

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

- Be careful driving or operating machinery until you know how this drug affects you. If you feel dizzy after taking this medicine, do not drive, operate machinery or do anything else that could be dangerous.
- If you drink alcohol, your blood pressure may drop, making you feel dizzy or faint.

SIDE EFFECTS

Like all nitrate preparation, Isomonit can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Common:

- Headache
- Hypotension (low blood pressure), symptoms include dizziness, nausea, vomiting

The above side effects usually subside with continued use of Isomonit.

Uncommon: (occurs in less than 1%)

- Aggravation of chest pain, abnormal heart beat, rapid heartbeat, fainting
- Rash, redness
- Abdominal pain, diarrhoea, indigestion
- Difficulty in urinating or frequent urinating, impotence
- Joint pain
- Agitation, anxiety, confusion, loss of coordination, loss of sensation, increased appetite, insomnia, nervousness, nightmares
- Bronchitis, pneumonia, upper respiratory tract infection.
- Loss of strength, blurred vision, cold sweat, visual disturbance, swelling due to fluid retention, malaise, neck stiffness, shivering

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

STORAGE AND DISPOSAL OF ISOMONIT

Storage

Keep medicines in original packaging. Store in a cool (below 25°C), dry place, away from direct heat and light and excessive moisture.

Do not leave your medicine in the car. Keep all medicines out of the reach of children.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

PRODUCT DESCRIPTION

What it looks like

White, round and biplain tablet, with a score notch on one side.

Ingredients

Active ingredient

Each tablet contains 60mg of Isosorbide- 5-mononitrate.

Inactive ingredients

Methylhydroxypropylcellulose, lactose monohydrate, polyvidone, talc, microcrystalline cellulose, calcium hydrogen phosphate, magnesium stearate, colloidal silicon dioxide.

Packing

Blisters of 10 x 10's tablets per box.

MAL Number

MAL19983983AC

MANUFACTURER

Manufactured by:

Rottendorf GmbH
Ostenfelder Str. 51 - 61
59320 Ennigerloh

For

Hexal AG
Industriestraße 25,
83607 Holzkirchen,
Germany.

PRODUCT REGISTRATION HOLDER

IMEKS Pharma Sdn Bhd.
No.5&9, Jalan Udang Harimau 2,
Medan Niaga Kepong,
51200 Kuala Lumpur, Malaysia.

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