

Isomonit Retard 60mg Prolonged Release Tablets

Isosorbide mononitrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Isomonit Retard is and what it is used for
2. What you need to know before you take Isomonit Retard
3. How to take Isomonit Retard
4. Possible side effects
5. How to store Isomonit Retard
6. Contents of the pack and other information

1 What Isomonit Retard is and what it is used for

Isomonit Retard contains the active substance isosorbide mononitrate which belongs to a group of medicines called nitrate vasodilators. These work by relaxing the blood vessels of the heart, reducing the strain on the heart making it easier to pump blood.

Isomonit Retard may be used to **prevent an attack of angina pectoris** (heart cramp, chest pain).

Isomonit Retard is not suitable for the treatment of acute attacks of angina pectoris.

2 What you need to know before you take Isomonit Retard

Do not take Isomonit Retard if you:

- are **allergic** to
 - isosorbide mononitrate or,
 - any of the other ingredients of this medicine listed in section 6
 - other nitrates (the group of medicines that isosorbide mononitrate belongs to)
- have any condition where your **blood pressure is very low** or your blood is **not circulating properly**
- have suffered from a **head injury** or **bleeding** in the brain
- are suffering from shock as the blood has stopped circulating properly around your body (circulatory failure)
- have a heart problem called cardiomyopathy, pericarditis or you have narrow heart valves
- have severe **anaemia** (low level of red blood cells)
- are taking a medicine for male erectile dysfunction e.g. sildenafil.

Warning and precautions

Talk to your doctor or pharmacist before taking Isomonit Retard if you:

- have had a heart attack or other heart conditions e.g. heart failure

- an **under-active thyroid gland**
- have a **very low body temperature** (hypothermia)
- suffer from **malnutrition**
- have severe **kidney** or **liver** problems

Children and adolescents

Isomonit Retard should not be given to children

Other medicines and Isomonit Retard

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

Especially:

- medicines to treat high blood pressure such as **ACE inhibitors** (e.g. enalapril), **beta-blockers** (e.g. atenolol), **calcium channel blockers** (e.g. nifedipine) or **water tablets** (e.g. furosemide)
- **sildenafil, tadalafil** or **vardenafile**, used to treat male erectile dysfunction, **must not be taken** if taking nitrate preparations such as Isomonit Retard
- **dihydroergotamine** used to treat migraines
- **alcohol**
- **NSAID** and **acetylsalicylic acid** may reduce the response of Isomonit Retard.

Isomonit Retard with food, drink and alcohol

You are advised **not** to drink alcohol with this medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You may experience side effects such as dizziness when taking Isomonit Retard. Do not drive or operate machinery if you are affected.

Isomonit Retard contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take Isomonit Retard

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets **with water**, you can take them with or without food.

You should take the daily dose in the morning.

The recommended dose is:

Adults:

The usual starting dose is 1 tablet once daily. If necessary, your doctor may increase the dose to 2 tablets once daily.

Children and adolescents:

Isomonit Retard should not be given to children.

In the event of an acute attack, sublingual or buccal glyceryl trinitrate tablets or spray should be used.

If you take more Isomonit Retard than you should

- talk to a doctor or go to a hospital straightaway.
- take the medicine pack with you so that the doctor knows what you have taken.
- you may develop excitation, higher heartbeat, low blood pressure, flushing, cold perspiration, nausea, vomiting, vertigo, faint or pulsing headache.

If you forget to take Isomonit Retard

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Isomonit Retard

Do not stop taking Isomonit Retard without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. At the start of treatment, some people may suffer from headaches, feeling sick or dizziness but these problems usually disappear with time.

Other side effects include:

Common: may affect up to 1 in 10 people

- low blood pressure. This may make you feel faint or dizzy.
- faster heartbeat
- headache
- feeling dizzy
- feeling sick

Uncommon: may affect up to 1 in 100 people

- vomiting
- diarrhoea

Rare: may affect up to 1 in 1,000 people

- rash
- fainting
- itching

Very rare: may affect up to 1 in 10,000 people

- muscle pain

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Isomonit Retard

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Isomonit Retard contains

- The active substance is isosorbide mononitrate.
Each prolonged release tablet contains 60mg isosorbide mononitrate.
- The other ingredients are lactose monohydrate, hypromellose, colloidal anhydrous silica, povidone 25000, talc, microcrystalline cellulose, calcium hydrogen phosphate, magnesium stearate.

What Isomonit Retard looks like and contents of the pack

Isomonit Retard 60mg Prolonged Release tablets are round, white biplane prolonged release tablets with a one-sided score notch and a facet.

PVC/Aluminium blister: 30 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Rowex Ltd., Bantry, Co. Cork, Ireland

Manufacturer:

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.
Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.

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