

Package leaflet: Information for the user

Isoket Retard 40 mg Tablets Isosorbide dinitrate

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Isoket Retard is and what it is used for

Isoket Retard belongs to a group of medicines called organic nitrates. Organic nitrates work by widening the blood vessels in your heart to allow an increased amount of blood to flow to areas which need it.

Isoket Retard is used to prevent and treat angina pectoris. Angina usually feels like a tight pain in the chest, neck or arm area. The pain comes from the heart muscle and is a sign that part of it is not getting enough oxygen for the amount of work it is doing.

2. What you need to know before you take Isoket Retard

Do not take Isoket Retard if:

- You are allergic to isosorbide dinitrate, other nitrates or any of the other ingredients of this medicine (listed in section 6)
- You suffer from anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- You have had a heart attack (myocardial infarction)
- You have had a brain haemorrhage (bleeding)
- You have had a head injury (trauma)
- You have a low blood volume (hypovolaemia)
- You have very low blood pressure
- Your blood has stopped circulating around your body properly (circulatory failure).
- You take sildenafil (“Viagra”) or any other phosphodiesterase inhibitor.
- You take products that contain riociguat, a medicine used in treating pulmonary hypertension.

Warnings and precautions

- Talk to your doctor or pharmacist before taking Isoket Retard if: You have hypothyroidism (an underactive thyroid gland which can cause tiredness or weight gain)
- You are malnourished (severely underfed)
- You have liver or kidney disease
- You suffer from hypothermia (a very low body temperature)
- You suffer from very poor circulation
- You have been diagnosed with any of the following heart conditions: hypertrophic obstructive cardiomyopathy (HOCM), constrictive pericarditis, cardiac tamponade, low cardiac filling pressures, aortic/mitral valve stenosis and diseases associated with raised intra-cranial (head) pressure.
- You have an abnormally low level of oxygen in the blood and impaired gas exchange due to lung disease or ischaemic heart disease

- **Other medicines and Isoket Retard** Do not take Isoket Retard with phosphodiesterase inhibitors such as Sildenafil (“Viagra”), used for impotence. Using Isoket Retard with these medicines could cause your blood pressure to fall to a dangerously low level. You must not stop taking Isoket Retard to take Sildenafil as this will increase your chances of having an angina attack.
- **Do not take Isoket Retard with products that contain riociguat.**

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including: Medicines to lower your blood pressure.
- Monoamine oxidase inhibitors (used to treat depression)
- Tricyclic antidepressants (used to treat depression) and neuroleptics (used to treat anxiety).
- Ergotamine used for migraine.
- Sapropterin used for phenylketonuria (PKU).
- Any other medicine, including medicines obtained without a prescription.

Isoket with alcohol

Do not drink alcohol. It could increase the effect of Isoket and lower your blood pressure too much. If this happens, you may feel dizzy or faint.

Pregnancy and breast-feeding

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

Isoket may give you a headache, or make you feel dizzy or tired. If this happens to you, do not drive or operate machinery.

Isoket Retard contains lactose

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 Isoket Retard

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

Important: Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Remember: You should not chew the tablets, swallow them whole with a glass of water.

Adults

- The usual dose is one or two tablets per day. If you are taking two tablets, it is important to take the second tablet six to eight hours after the first. Taking the tablets in this way allows a period of time (when you are sleeping) when no tablets are taken. This is called a “nitrate low” period and is needed to make sure your medicine remains effective.

Use in children

This medicine is not suitable for children.

If you take more Isoket Retard than you should

Do not take more Isoket Retard than you should. If you accidentally take too much, immediately contact the nearest hospital casualty department or your doctor.

Too much Isoket Retard may cause your blood pressure to fall too low, making you feel sick, faint and dizzy. A very large overdose could cause a coma or collapse and require immediate resuscitation.

If you forget to take Isoket Retard

Do not take a double dose to make up for a forgotten dose. Take your next dose at the usual time.

If you stop taking Isoket Retard

Do not stop taking Isoket Retard without first talking to your doctor. You should keep taking your medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the tablets your condition may get worse.

If you have any further questions about 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.

Stop taking this medicine and seek immediate medical help if you have any of the following symptoms:

- **Swelling of the face or throat, causing difficulty in breathing or wheezing**
- **Fainting or collapse**
- **Swelling or blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).**

Speak to your doctor or pharmacist if you have any of the following symptoms:

Very common (may affect more than 1 in 10 people):

- Mild headaches at the start of treatment.

Usually they disappear after a few days.

Common (may affect up to 1 in 10 people):

- Dizziness
- Tiredness
- Feeling weak
- Fast heartbeat

They may occur for the first few days of treatment or after your dosage has been increased.

Uncommon (may affect up to 1 in 100 people):

- Feeling sick or being sick
- Skin rashes or flushing
- Looking pale
- Excessive sweating
- Restlessness
- Worse angina.

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

- Heartburn
- Red or scaly skin (exfoliative dermatitis)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Isoket 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. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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

6. Contents of the pack and other information

What Isoket Retard contains

The active substance is isosorbide dinitrate 40 mg.

The other ingredients are lactose monohydrate, talc, polyvinyl acetate, magnesium stearate and potato starch.

What Isoket Retard looks like

Isoket Retard is a white tablet marked with IR/40 on the front and SCHWARZ PHARMA on the back. They come in blister packs of 50, 56, 60, 84 and 90 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Norgine Pharmaceuticals Limited
Norgine House, Widewater place, Moorhall Road,
Harefield, Middlesex, UB9 6NS, UK

Manufacturer

Aesica Pharmaceuticals GmbH, Alfred Nobel Strasse 10, D-40789, Monheim, Germany

This leaflet was last revised in April 2019

If this leaflet is difficult to see or read or you would like it in a different format, please contact

Norgine Pharmaceuticals Limited
Norgine House, Widewater place, Moorhall Road,
Harefield, Middlesex, UB9 6NS, UK