

Isoket® 0.5 mg/ml

solution for infusion or injection

Isosorbide Dinitrate

Patient Information Leaflet

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- In this leaflet, Isoket 0.5 mg/ml solution for infusion or injection will be called Isoket.

In this leaflet:

1. What Isoket is for
2. Before you use Isoket
3. How to use Isoket
4. Possible side effects
5. How to store Isoket
6. Further information.

1. What Isoket is for

Isoket 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 is used to treat heart failure (heart problems that can cause shortness of breath or ankle swelling) and angina pectoris.

Angina usually feels like a tight pain in the chest, neck or arm area.

It is also used sometimes during surgical procedures on the heart.

2. Before you use Isoket

Do not use Isoket if:

- You are allergic to isosorbide dinitrate, other nitrates or any of the other ingredients of Isoket (see 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 brain haemorrhage (bleeding)
- You have had a head injury (head trauma) or raised intracranial pressure (high pressure within your skull)
- 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 have cardiogenic shock (your heart is not delivering enough oxygen around your body)
- You have constrictive pericarditis (inflammation of the sack-like covering of the heart)
- You have cardiac tamponade or hypertrophic obstructive cardiomyopathy (conditions which affect the ability of your heart to function as a pump)

- You have aortic or mitral valve stenosis (narrowing of the heart valves)
- You have an eye disease called glaucoma
- You take sildenafil (“Viagra”) or any other phosphodiesterase inhibitor.

If any of the above applies to you talk to your doctor or pharmacist.

Check with your doctor before using Isoket 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 have other heart problems or a family history of heart problems
- You suffer from orthostatic syndrome, (where you may have a rapid heart rate and light-headedness on standing)

Taking other Medicines

- **Do not take Isoket with phosphodiesterase inhibitors such as Sildenafil (“Viagra”) used for impotence. Using Isoket with these medicines could cause your blood pressure to fall to a dangerously low level.**

Tell your doctor if you are taking any of the following medicines:

- Medicines to lower your blood pressure. They could increase the effect of Isoket and lower your blood pressure too much.
- Tricyclic antidepressants (used to treat depression) and neuroleptics (used to treat anxiety). These may also increase the effect of Isoket.
- Dihydroergotamine (used to treat migraine). This could increase your blood pressure too much.
- Any other medicine, including medicines obtained without a prescription.
- Sapropterin used for phenylketonuria (PKU).

If any of the above applies to you, talk to your doctor or nurse.

Using Isoket with food or drink

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, trying to become pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking Isoket. Your doctor will decide whether you should take 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.

Warnings about the ingredients in Isoket

Isoket 0.5 mg/ml contains 3.54 mg/ml of sodium and may not be suitable for people on a controlled sodium diet. Tell your doctor or pharmacist before taking Isoket if this applies to you.

3. How to use Isoket

Important:

Your doctor will choose the dose that is right for you. If you have any questions ask your doctor.

Isoket is for intravenous infusion (injected into a vein) and intracoronary injection (injected directly into the artery serving the heart).

Your doctor or nurse will dilute Isoket with either saline (salt water) or glucose solution before it is given to you.

Adults

- When this medicine is given intravenously (injected into a vein), the usual dose will be between 2 mg and 12 mg per hour, although sometimes as much as 20 mg per hour is necessary.
- When used during surgical procedures on the heart the usual dose is 1 mg injected directly into the heart. Further doses may be given if your doctor thinks it necessary.

As this medicine is used in hospital, your heart beat (pulse) and blood pressure will be carefully monitored whilst you are being given Isoket. This is to make sure that your medicine is working properly and that the dose you are taking is right for you.

Children

This medicine is not suitable for children.

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

If you think you have been given too much Isoket

As this medicine will be given to you by a doctor or nurse, it is unlikely that you will be given too much or too little.

An overdose of Isoket may cause your blood pressure to be too low resulting in paleness, sweating, weak pulse, fast heartbeat, light-headedness on standing, headache, weakness, dizziness, feeling sick, being sick and diarrhoea. If you have any concerns about this tell your doctor or nurse.

4. Possible side effects

Like all medicines Isoket can cause side effects, although not everybody gets them.

- headache
- feeling sick
- have a faster heart beat (tachycardia)
- a reduced blood flow to the brain and heart, causing you to feel faint or dizzy
- drowsiness
- weakness
- light-headedness on standing
- fainting
- symptoms of angina (chest pain) may be increased
- skin rash or flushing
- heartburn.

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.

5. How to store Isoket

Keep out of the reach and sight of children.

Do not use Isoket after the expiry date on the carton. The expiry date refers to the last day of that month. This medicine does not require any special storage conditions. Once opened the product should be used immediately. Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

6. Further information

What Isoket contains

The active substance is isosorbide dinitrate.
Isoket contains 0.5 milligrams of isosorbide dinitrate in each ml of solution.

The other ingredients are sodium chloride, water for injections and hydrochloric acid and sodium hydroxide for pH adjustment.

What Isoket looks like

Isoket is a solution for infusion and injection. It is a clear solution.

In Ireland

Isoket 0.5 mg/ml comes in glass bottles containing 25 mg of isosorbide dinitrate in 50 ml of solution.

In the UK

Isoket 0.5 mg/ml comes in a glass bottle or syringe. The bottles contain 25 mg of isosorbide dinitrate in 50 ml of solution. Each syringe contains 5 mg of isosorbide dinitrate in 10 ml of solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Merus Labs Luxco II S.à.R.L. 26-28, rue Edward Steichen L-2540 Luxembourg

Manufacturer

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

This leaflet was last updated

If this leaflet is difficult to see or read or you would like it in a different format, please contact UCB Pharma Ltd, 208 Bath Rd, Slough, Berkshire, SL1 3WE, UK

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The following information is intended for medical or healthcare professionals only.

It supplements the information provided above in Section 3.

Posology and Method of Administration

Adults, including the elderly

Intravenous route

Isoket 0.5 mg/ml is intended for intravenous administration by slow infusion via a syringe pump.

A dose of between 2 mg and 12 mg per hour is usually satisfactory. However, dosages up to 20 mg per hour may be required. In all cases the dose administered should be adjusted to the patient response.

Intra-coronary Route

The usual dose is 1 mg given as a bolus injection prior to balloon inflation. Further doses may be given not exceeding 5 mg within a 30 minute period.

Children

The safety and efficacy of Isoket has not been established in children.

Admixtures are stable for approximately 24 hours at room temperature in the recommended containers.

Open ampoules or bottles should be used immediately and any unused drug discarded.

Incompatibilities

Isoket contains isosorbide dinitrate in isotonic solution and is compatible with commonly employed infusion fluids, such as sodium chloride solution, 5-30% glucose solution, Ringer's solution and solutions containing albumin. No incompatibilities have so far been demonstrated.

Isoket is compatible with glass infusion bottles and infusion packs made from polyethylene.

Isoket may be infused slowly using a syringe pump with glass or plastic syringe. The use of PVC giving sets and containers should be avoided since significant losses of the active ingredient by adsorption can occur.

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