

Package Leaflet: Information for the user
Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion

Isosorbide Dinitrate

Read all of this leaflet carefully before you start using 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.
 - If you get any side effects, talk to your doctor or pharmacist.
- This includes any possible side effects not listed in this leaflet.



What is in this leaflet:

1. What Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion is and what it is used for
2. What you need to know before you are given Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion
3. How to use Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion
4. Possible Side Effects
5. How to store Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion
6. Contents of the pack and other information

1. What Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion is and what it is used for

Isosorbide dinitrate, the active ingredient, belongs to a group of medicines called vasodilators used in the treatment of heart disease. It works by widening the arteries and veins so decreasing the resistance to blood flow and lowering blood pressure.

This medicine is a concentrated solution for injection or infusion and is used for the treatment of heart problems. It is specifically used for:

- Treatment of severe chest pain (angina) which may start suddenly and gets increasingly worse
- Treatment of heart failure, which may have occurred after a heart attack
- Surgical procedures treating narrowing of heart arteries

2. What you need to know before you use Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion

Please tell your doctor if you are taking any other medication.

DO NOT use Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion if:

- You are allergic to isosorbide dinitrate or any other medication containing nitrate, mononitrate or dinitrate or any of the other ingredients listed in this medicine (listed in section 6)
 - You have ever had a ruptured blood vessel in your brain (cerebral haemorrhage)
 - You have had a head injury (head trauma) or raised intracranial pressure (high pressure within your skull)
 - You suffer from anaemia (reduced number of red blood cells or iron level)
 - You have 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 a low blood volume because of injury or another reason
 - You have an eye disease called glaucoma
 - You have been taking sildenafil or any other phosphodiesterase inhibitor
- If any of the above applies to you talk to your doctor or pharmacist.

Warnings and Precautions

Talk to your doctor or pharmacist before using Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion if:

- You are pregnant or breastfeeding
- You have hypothyroidism (an underactive thyroid gland which can cause tiredness or weight gain)
- You are malnourished (severely underfed)
- You suffer from hypothermia (a very low body temperature)
- You suffer from liver or kidney disease
- 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)

Other medicines and Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

You should not be given Isosorbide Dinitrate with phosphodiesterase inhibitors such as Sildenafil ("Viagra") used for impotence. Using Isosorbide Dinitrate with these medicines could cause your blood pressure to fall to a dangerously low level.

It is especially important to tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines to lower your blood pressure. They could increase the effect of Isosorbide Dinitrate 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 Isosorbide Dinitrate.
- 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).

Using Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion with alcohol

Do not drink alcohol. It could increase the effect of Isosorbide Dinitrate 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 being given Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion. Your doctor will decide whether you should be given this medicine.

Driving and using machines

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

Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion contains Sodium Chloride

This medicine contains less than 1mmol sodium (23mg) per 1mg per 1mL, that is to say it is essentially 'sodium-free'.

Signature

**Additional information for Healthcare Professionals
(as stated on the Summary of Product Characteristics)**

Therapeutic indications

- Treatment of unresponsive left ventricular failure, secondary to acute myocardial infarction.
- Unresponsive left ventricular failure of various aetiologies.
- Severe or unstable angina pectoris.
- To facilitate or prolong balloon inflation and to prevent or relieve coronary spasm during percutaneous transluminal coronary angioplasty.

Posology and method of administration

Dosage: Adults, including the elderly.

Isosorbide Dinitrate is a concentrated solution. It should never be injected directly and must be diluted.

Avoid administration through PVC or PU tubing and giving sets, because of adsorption of ISDN onto plastic.

3. How to use Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion

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

The doctor will decide what dose of this medicine you should be given. Check the label carefully. If you are not sure, ask your doctor, nurse or pharmacist.

This medicine must be diluted before use with sodium chloride or glucose. It should never be used undiluted.

The recommended dose is:

Adults

This medicine is either given by infusion into a vein or by direct injection into the coronary artery. Doses will be adjusted by your doctor, but the usual dose is between 2mg and 12mg per hour, although sometimes as much as 20mg per hour is necessary. The normal dose for direct injection into the coronary artery is 1mg. Further doses may be given if your doctor thinks it necessary.

The injection is for single use only, so once the ampoule or vial is opened the medicine should be used immediately and any unused medicine discarded.

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

Use in 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 are given more Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion than you should

Tell your doctor as soon as possible. If you are a medical practitioner administering this medicine please refer to the Summary of Product Characteristics.

An overdose of Isosorbide Dinitrate 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.

If a dose of Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion is not given at the correct time

The dose should be given as soon as it is remembered. The next dose should be given at the usual time. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Stop taking this medicine and tell your doctor immediately if you experience:

- Swelling of the face, lips or throat which makes it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of severe allergic reaction.
- Fainting which is sometimes accompanied by a slowing heartbeat
- Swelling of the face or blistering of the skin, mouth, eyes or genitals (Stevens-Johnson syndrome)

Other side effects

- Headache
- Drowsiness
- Weakness
- Nausea
- Feeling faint or dizzy as this may be caused by a reduced blood flow to the brain and heart
- Skin rash or flushing
- Dizziness
- Increased heartbeat
- Light-headedness on standing
- Vomiting
- Worsening symptoms of angina (chest pain)
- Heartburn

Your pulse and blood pressure may be monitored during administration (because of these effects).

Tell your doctor, nurse or pharmacist immediately if you think you have any of these, or other problems.

Reporting of Side Effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: Website: 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 Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion

- Keep this medicine out of the sight and reach of children.
- The medicine has an expiry date printed on the ampoule or vial and carton label. Do not use the medicine after the expiry date. Before use the doctor or nurse will check the medicine has not passed this date and that the medicine does not show any sign of deterioration. The expiry date refers to the last day of the month.
- After the expiry date, return any unused medicine to a pharmacy.
- Only use this medicine if it is particle free.
- This medicine is for single use only, so once the ampoule or vial is opened the medicine should be used immediately and any unused medicine discarded.
- Keep the container in the outer carton to protect it from light.
- Do not throw away any medicines via waste water. These measures will help to protect the environment.

6. Contents of the pack and other information

What Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion contains

- The active substance is isosorbide dinitrate at a strength of 1mg in 1mL.
- The other ingredients are sodium chloride and Water for Injections.

What Isosorbide Dinitrate 0.1% w/v Concentrate for Solution for Injection or Infusion looks like and contents of the pack

This medicine is a clear and colourless solution. This medicine comes in 10mL single use ampoules and 50mL single use vials. The medicine is packed into cartons containing 10 ampoules, 1 vial or 10 vials. Both pack sizes of vials may not be available at the same time.

Marketing Authorisation Holder and Manufacturer:

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Intravenous administration: Dosage should be adjusted according to patient response. Typically, a dose of between 2mg and 12mg per hour is suitable, although doses of up to 20mg per hour may be necessary.

Prepared admixtures are always given by intravenous infusion or using a syringe pump incorporating a glass or rigid plastic syringe. The patient's blood pressure and pulse should be monitored closely during administration.

Intracoronary administration: A dilution of 50% is recommended. The usual dose is 1mg given as a bolus injection prior to balloon inflation. Additional doses may be given, not exceeding 5mg over 30 minutes.

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

Isosorbide Dinitrate is presented in 10mL ampoules and 50mL vials intended for single use only.

Incompatibilities The use of polyvinyl chloride (PVC) or polyurethane (PU) giving sets and containers should be avoided as significant losses of the active ingredient by adsorption can occur.

Materials made of polyethylene (PE), polypropylene (PP) or polytetrafluoroethylene (PTFE) have been proven to be suitable for infusing this medicine.