

Package leaflet: Information for the patient

Isosorbide Dinitrate Tablets 10 mg and 20 mg Isosorbide dinitrate

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

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

1. What Isosorbide Dinitrate Tablets is and what it is used for

Isosorbide Dinitrate Tablets contain isosorbide dinitrate which is a nitrate vasodilator.

Nitrate vasodilators cause the blood vessels to widen which helps the heart to pump blood through the blood vessels. They may also improve blood supply to the heart itself.

They are used to:

- prevent angina (chest pain), which occurs when there is an inadequate supply of oxygen for the work the heart is performing
- treat the symptoms of congestive heart failure.

These tablets are not suitable for treating an attack that has already started as the tablets will not work quickly enough.

2. What you need to know before you take Isosorbide Dinitrate Tablets

Do not take Isosorbide Dinitrate Tablets:

- if you are allergic to isosorbide dinitrate, to any other nitrate medicines or to any of the other ingredients of this medicine (listed in section 6)
- if you take medicines for male erectile problems (e.g. sildenafil, tadalafil, or vardenafil). Taking these medicines with isosorbide dinitrate may cause a dangerous fall in blood pressure and result in collapse, unconsciousness and could be fatal
- if you have suffered a heart attack or shock
- if you have heart problems such as those affecting the valves or walls of the heart
- if you have severely low blood pressure
- if you have low blood volume for any reason
- if you have severe anaemia
- if you have had a head injury, have increased pressure on the brain or bleeding in the brain.

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

Warnings and precautions

Talk to your doctor before taking Isosorbide Dinitrate Tablets:

- if you have an underactive thyroid gland (fatigue, weight gain, constipation, feeling cold, dry skin, hair problems)
- if you suffer from hypothermia (feeling cold with pale looking skin and low body temperature)
- if you are malnourished (are undernourished)
- if you suffer from increased pressure in the eye(s) (glaucoma)
- if you have severe liver or kidney problems
- if you have a tendency to feel dizzy or faint on standing up quickly
- if you have been taking nitrate or nitrite medicines similar to Isosorbide Dinitrate Tablets.

Other medicines and Isosorbide Dinitrate Tablets

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

- Medicines used to treat male erectile problems (see 'Do NOT take' Section above)
- Medicines containing alcohol (see ' Isosorbide Dinitrate Tablets with alcohol' section below for symptoms of use with alcohol)
- Medicines used to reduce blood pressure (e.g. ACE-inhibitors, beta-blockers, calcium antagonists, vasodilators, angiotensin II antagonists)
- Alprostadil (for male erectile problems)
- Tricyclic antidepressants (used to treat depression)
- Neuroleptics (used to treat some psychiatric illnesses and severe anxiety)
- Aldesleukin (for kidney cancer)
- Medicines mainly used in hospitals, containing noradrenaline, acetylcholine or histamine.

Isosorbide Dinitrate Tablets with alcohol

Drinking alcohol or taking medicines which contain alcohol while taking these tablets may cause these tablets to lower your blood pressure too much, or you may find that alcohol has more effect than usual.

Pregnancy, breast-feeding and fertility

If you are pregnant, trying to become pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking Isosorbide Dinitrate Tablets.

Driving and using machines

Isosorbide Dinitrate Tablets may cause headache, tiredness and dizziness, especially when you first start taking them. If any of these occur do not drive, use machinery, or perform any tasks that may require you to be alert.

Isosorbide Dinitrate Tablets contains lactose and sucrose

This medicine contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Isosorbide Dinitrate Tablets

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

Swallow the tablets whole with water.

The recommended dose is 1 or 2 tablets three or four times daily.

Take at the times directed by your doctor or pharmacist, to allow a "nitrate free" period (usually when you are sleeping) when no tablets are taken. This is to prevent your tablets from becoming less effective.

Use in children

This medicine is not suitable for children.

If you take more Isosorbide Dinitrate Tablets than you should

Do not take more Isosorbide Dinitrate Tablets than you should, If you accidentally take more tablets than you should, you may feel very drowsy or faint. If this happens it could mean your blood pressure is low; lie down and raise your legs.

1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take your tablets pack and any remaining tablets with you so that people can see what you have taken.
3. Do this even if you feel well.

If you forget to take Isosorbide Dinitrate Tablets

If you forget to take a dose take it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.

Do not take a double dose to make up for a missed dose.

If you stop taking Isosorbide Dinitrate Tablets

Do not stop taking these tablets, or lower the dose, without first checking with your doctor.

Keep taking your tablets until the doctor tells you to stop.

Do not let yourself run out of medicine especially over the weekend or on holidays.

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

4. Possible side effects

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

STOP taking the tablets and **seek medical help immediately** if you have any of the following **allergic reactions**:

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps
- blistering of the mouth, eyes, or genital region, patchy areas of rash, peeling skin.

Seek immediate medical attention if you have any of the following symptoms:

- nausea, vomiting, feeling restless, sweating, looking pale, or feeling faint. This may be due to very low blood pressure
- angina pain which is worse than usual.

Tell your doctor if you get the following symptoms. These side effects may reduce or disappear with time:

Very common side effects (affects more than 1 in 10 people)

- headache

Common side effects (affects less than 1 in 10 people)

- light-headedness or dizziness (especially on standing up)
- tiredness, feeling weak
- rapid heart rate

Uncommon side effects (affects less than 1 in 100 people)

- mild skin rashes
- flushing

- nausea or vomiting

Other side effects (unknown frequency)

- heartburn.

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 the 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 Isosorbide Dinitrate Tablets

Keep this medicine out of sight and reach of children.

Do not take after the expiry date which is stated on the label and on the carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

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

6. Contents of the pack and other information

What Isosorbide Dinitrate Tablets contains

- The active substance is isosorbide dinitrate (10 mg or 20 mg).
- The other ingredients are: lactose monohydrate, compressible sugar (which contains sucrose), colloidal silicon dioxide and magnesium stearate. (See end of Section 2 for further information on lactose and sucrose).

What Isosorbide Dinitrate Tablets look like and contents of the pack

- Isosorbide Dinitrate Tablets 10 mg are white round tablets marked 'IDN 10' on one side.
- Isosorbide Dinitrate Tablets 20 mg are white round tablets marked 'IDN 20' on one side.

They are available in white or grey plastic containers of 30, 56, 60, 90, 100, 120, 180 and 240 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chemidex Pharma Ltd, trading as Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey TW20 8RB.

Manufacturer

Lelypharma B.V., Zuiveringweg 42, 8243 PZ Lelystad, the Netherlands.

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