

Isosorbide Dinitrate 10mg and 20mg Tablets

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

- Keep this leaflet. You may need to read it again.
- 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.
- If you have any further questions, ask your doctor or pharmacist.
- If you have any of the side effects, or if you notice any not listed, please tell your doctor or pharmacist.

In this leaflet:

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1. What Isosorbide Dinitrate tablets are and what they are used for

Isosorbide Dinitrate 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.

Isosorbide Dinitrate tablets may be used to:

- relieve the pain and frequency of angina attacks.
- help control certain types of heart failure.

2. Before you take Isosorbide Dinitrate tablets

Do not take Isosorbide Dinitrate tablets if you:

- are **allergic** (hypersensitive) to isosorbide dinitrate, isosorbide mononitrate or any of the ingredients in the tablet (see section 6). An allergic reaction may include a rash, itching or difficulty breathing
- have any condition where your **blood pressure is very low** or your blood is **not circulating properly** (such as shock)
- suffer from **haemorrhage** (problems with bleeding)
- are **dehydrated** due to illness such as diarrhoea or being sick
- have **heart problems** such as heart valve problems, inflammation of the heart surface, build up of fluid under the surface of the heart or progressive heart failure due to long term lung disease
- have angina that is caused by an **enlarged heart muscle**
- have raised **pressure in your head**
- have severe **anaemia**.

Check with your doctor or pharmacist before taking Isosorbide Dinitrate tablets if you:

- have **glaucoma** (increased pressure in the eye)
- have any **serious damage to your heart** (such as after a heart attack or operation)
- have been told you suffer from deficiency of an enzyme called glucose 6 phosphate dehydrogenase (**G6PD**). This condition is sometimes called "Favism" (it is a form of anaemia that is more common in Mediterranean people, attacks may occur after eating certain foods, such as broad beans)
- have severe **kidney** or **liver** problems
- have an **underactive thyroid** gland
- are **undernourished** as a result of a poor diet
- are suffering from **hypothermia**
- have suffered from a **head injury** or **bleeding** in the brain.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- **noradrenaline** (norepinephrine) – to treat high blood pressure or heart attack
- **acetylcholine** – used in some operations
- medicines to treat high blood pressure such as **calcium channel blockers** (e.g. nifedipine)
- **tricyclic** antidepressants (e.g. amitriptyline)
- **phenothiazines** (e.g. chlorpromazine) – to treat mental illness
- **histamine** – to treat allergic reactions
- **sildenafil, tadalafil** or **vardenafil**, used to treat male erection dysfunction, should not be taken if taking nitrate preparations such as Isosorbide Dinitrate tablets because a severe and possibly dangerous fall in blood pressure can occur. This would result in collapse, unconsciousness and could be fatal.

Pregnancy and breastfeeding

If you are pregnant, planning to become pregnant or breastfeeding speak to a doctor before taking Isosorbide Dinitrate tablets.

Taking Isosorbide Dinitrate tablets with alcohol
You are advised **not** to drink alcohol with this medicine.

Sugar intolerance

If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

If you see another doctor or go into hospital, let them know what medicines you are taking.

3. How to take Isosorbide Dinitrate tablets

Always take Isosorbide Dinitrate tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the tablets **with water**.

The usual doses are:

• Adults

- Angina: 30-120mg daily in divided doses
- Heart failure: 40-160mg daily in divided doses. Your doctor may also be treating you with other drugs.

The maximum daily dose is 240mg in divided doses.

• Elderly

- a lower dose may be given particularly if you have kidney or liver disease.

If you take more Isosorbide Dinitrate tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take Isosorbide Dinitrate tablets

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.

4. Possible side effects

Like all medicines, Isosorbide Dinitrate tablets can cause side effects, although not everybody gets them.

Contact your doctor immediately if you notice signs of: allergic skin reactions, skin that is red, flaky or peeling (exfoliative dermatitis), severe form of skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson Syndrome) and swelling of the face, lips, tongue or throat (angioedema).

Please tell your doctor or pharmacist if you notice any of the following effects or any not listed:

Very common (occurs in more than 1 in 10 users):

- headache (especially when you first start taking Isosorbide Dinitrate tablets).
- flushing.

Common (occurs in less than 1 in 10 users):

- a decrease in blood pressure, dizziness or faintness when standing up due to low blood pressure, a racing heart beat, drowsiness, dizziness and weakness may also occur (especially when Isosorbide Dinitrate tablets are used for the first time or when your dose is increased).
- swelling of the hands, ankles or feet.

Uncommon (occurs in less than 1 in 100 users):

- feeling or being sick.
- worsening of angina due to very low blood pressure.
- collapsing with slow or irregular heart beat and fainting.

Very rare (occurs in less than 1 in 10, 000 users):

- shallow and slow breathing causing low oxygen in the blood and a risk of heart attack in patients with heart disease.
- increased pressure in the eye (angle closure glaucoma).
- a type of tumour that affects the pituitary, may cause headaches or vision problems.

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

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

5. How to store Isosorbide Dinitrate tablets

Keep out of the sight and reach of children.

Store below 25°C, in a dry place.

Do not use Isosorbide Dinitrate tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Isosorbide Dinitrate tablets contain

- The active substance (the ingredient that makes the tablets work) is isosorbide dinitrate. Each tablet contains either 10mg or 20mg of the active ingredient.
- The other ingredients are magnesium stearate, maize starch, lactose, polyvidone.

What Isosorbide Dinitrate tablets look like and contents of the pack

Isosorbide Dinitrate tablets are circular, white to off white uncoated tablets

Pack size: 56

Marketing Authorisation holder and manufacturer

Accord, Barnstaple, EX32 8NS, UK

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