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Package leaflet: Information for the user

Isosorbide Mononitrate 20mg Tablets
Isosorbide Mononitrate 40mg Tablets

Read all of this leaflet carefully before you start taking 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 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 Isosorbide mononitrate Tablets are and what are they used for
2. What you need to know before you take Isosorbide mononitrate Tablets
3. How to take Isosorbide mononitrate Tablets
4. Possible side effects
5. How to store Isosorbide mononitrate Tablets
6. Contents of the pack and other information

1. What Isosorbide mononitrate Tablets are and what are they used for

Isosorbide mononitrate belong to a group of medicines called Nitrates. These tablets are used to relieve the symptoms of angina pectoris. Angina pectoris is a painful tightness in the chest, which occurs when the muscles of the heart are not receiving enough oxygen. Pain may also be felt in the neck and arms.

The tablets are used to prevent chest pain (angina) or to treat heart failure. It works by relaxing the blood vessels to the heart, so the blood and oxygen supply to the heart is increased.

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

Do not take Isosorbide mononitrate Tablets
- If you are allergic (hypersensitive) to isosorbide mononitrate or any of the other ingredients of this medicine(listed in section 6 and end of section 2)
- If you are also taking riociguat. See section "Other medicines and Isosorbide mononitrate Tablets
- If you have suffered a stroke or have any other condition which may affect the blood supply to your brain
- If you have very low blood pressure (hypotension)
- If you have been told that you have a problem with your heart. Ask your doctor if you are not sure if this applies to you.
- If you are being treated for severe anemia (low iron content in your body)
- If you have closed angle glaucoma (high pressure in eyes)
- If you have a disease or have suffered a head injury, that cause pressure or bleeding in the brain (raised intra-cranial pressure).
- If you are taking drugs used in erectile dysfunction e.g.

Phosphaodiesterase type-5 inhibitors such as sildenafil (Viagra), tadalafil and vardenafil.

Warnings and precautions

Talk to your doctor or pharmacist before taking Isosorbide mononitrate Tablets

Take special care with Isosorbide mononitrate Tablets

You should let your doctor know:
- If you have had a recent heart attack
- If you suffer from low blood pressure (hypotension)
- If you have a poor diet or do not have enough to eat (malnutrition)
- If you are suffering from low body temperature (hypothermia)
- If you have problems with your liver or kidneys
- If you suffer from hypothyroidism (underactivity of the thyroid gland)
- If you have alcohol problem as you should not drink with these tablets

Other medicines and Isosorbide mononitrate Tablets

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

Do not use Isosorbide mononitrate Tablets at the same time as riociguat since this can cause hypotension (abnormally low blood pressure).

Do not take medicines for erectile dysfunction e.g. sildenafil known as Viagra with Isosorbide mononitrate (see section 'Do not take Isosorbide mononitrate Tablets'). You should tell your doctor before taking these tablets if you are currently taking any of the following medicines:
- Beta-blockers, vasodilators (e.g. *alprostadail*), *aldesleukin* and Angiotensin II receptor antagonists e.g. *captopril, enalapril* used to reduce blood pressure.
- Tricyclic antidepressants e.g. *imipramine, amitriptyline*
- Medicines used to treat a mental condition, e.g. *chlorpromazine, risperidone, clozapine*
- Medicines used to treat migraine, e.g. Dihydroergotamine, as these tablets may increase the hypertensive effects of this medicine.

Pregnancy and breast-feeding

Do not take Isosorbide mononitrate Tablets if you are pregnant, planning to become pregnant or are breast feeding.
Ask your doctor for advice before taking any medicine.

Driving and using machines

You may experience dizziness, tiredness or blurred vision when you start taking Isosorbide mononitrate Tablets. You should therefore know how you react to these tablets before you drive or use machines.

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Isosorbide mononitrate Tablets 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 Isosorbide mononitrate Tablets

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

Dosage:
The usual oral adult dose to be taken orally is:-

Adults: One tablet to be taken two or three times a day. The dose may be increased to 120mg per a day. Always follow you doctor advice.

Elderly: The usual dose is same as the adult dose.

Children:
Not recommended for use in children

If you take more Isosorbide mononitrate Tablets than you should
If you (or someone else) swallow a lot of tablets at the same time, or you think a child has swallowed any these tablets, contact your nearest hospital casualty department or your doctor immediately. Take this leaflet and your tablets with you. The symptoms of an overdose are pulsing headache, reddening of skin, cold perspiration, nausea, vomiting and a fast heartbeat.

If you forget to take Isosorbide mononitrate Tablets
If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose though, do not take a double dose to make up for a forgotten dose.

If you stop taking Isosorbide mononitrate Tablets
Do not stop taking your tablets without first discussing this with your doctor as this may be harmful.
If you have any further questions on 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.
If you develop an allergic (hypersensitivity) reaction e.g. skin rash or itching, swelling of the face, lips, tongue or throat or difficulty breathing or swallowing then stop taking Isosorbide mononitrate Tablets and tell your doctor immediately.
A severe hypotensive response may occur with nausea, vomiting, restless pallor and excessive perspiration. Uncommonly collapse may occur.

Very common side effects: (affecting more than 1 in 10 patients)
- Headache (at the start of the treatment, you may have a headache. Usually this disappears after a few days)

Common: side effects: (affecting between 1 in 10 and 1 in 100 patients)
- Light headedness in the upright position
- Hypotension (low blood pressure)
- Dizziness, drowsiness, feeling weak
- Fast heart beat

Uncommon side effects: (affecting between 1 in 100 and 1 in 1,000 patients)
- Slow heart beat
- Fainting
- Worsening of chest pains

Infrequently: side effects: (<1% patients)
- Nausea and vomiting
- Flushing (reddening of the skin)
- Allergic skin reaction e.g. rash
- Change in heartbeat
- 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.

Reporting of side effects
If you get any side effects, talk to your doctor, 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: 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 mononitrate Tablets

Keep this medicine out of the sight and reach of children.
Store your tablets in the original package.
Do not store above 25°C
Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
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 to protect the environment.

6. Contents of the pack and other information

What Isosorbide mononitrate Tablets contains
The active substance is isosorbide-5-mononitrate.
- each 20mg tablet contains 20mg of Isosorbide mononitrate.
- each 40mg tablet contains 40mg of Isosorbide mononitrate.

The other Substances are: Microcrystalline cellulose, Lactose Monohydrate, Colloidial Anhydrate Silica, Maizestarch, Talc and Magnesium stearate.

What Isosorbide mononitrate Tablets look like and contents of the pack
The tablets are white to off white, round flat, embossed with '120' (20mg) or '140' (40mg) on one side.

They are available in blister packs of 56 and 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
MEDREICH PLC
Warwick House, Plane Tree Crescent,
Feltham TW13 7HF, United Kingdom
E-mail : info@medreich.co.uk

To request a copy of this leaflet in Braille, or large print, please call, 020 88311580 (UK only)
Please be ready to give the following information:

Product name	Reference number
Isosorbide mononitrate 20 mg tablets	PL 21880/0117
Isosorbide mononitrate 40 mg tablets	PL 21880/0118

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