

Package Leaflet: Information for the user

Isomex 30 mg prolonged-release tablets Isosorbide mononitrate

Read all of this leaflet carefully before you start taking 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.
- 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 Isomex is and what it is used for
2. What you need to know before you take Isomex
3. How to take Isomex
4. Possible side effects
5. How to store Isomex
6. Contents of the pack and other information

1. What Isomex is and what it is used for

Isomex contains the active ingredient isosorbide mononitrate, which belongs to a group of medicines called nitrates. This type of medicine works by widening blood vessels and thereby facilitates the heart's work for those with angina pectoris.

Isomex is used as preventive treatment of angina pectoris in adults.

2. What you need to know before you take Isomex

Do not take Isomex

- if you are allergic to isosorbide mononitrate or any of the other ingredients of this medicine (listed in section 6)
- if you are also taking medicines to treat impotence or pulmonary arterial hypertension (PAH); for example, Viagra (sildenafil), Cialis (tadalafil), or Levitra (vardenafil). See section "Other medicines and Isomex".
- if you suffer from failure of blood circulation (acute circulatory failure, shock)
- if you have a disease of the heart muscle (constrictive cardiomyopathy)
- if you have certain diseases of the pericardium (constrictive pericarditis, cardiac tamponade)
- if you have early signs of a heart attack (chest pain or pressure, pain spreading to your jaw or shoulder, nausea, sweating).
- if you are also taking riociguat. See section "Other medicines and Isomex".

Warnings and precautions

Talk to your doctor or pharmacist before taking Isomex:

- if you suffer from severely impaired blood flow in the brain
- if you have some form of heart disease
- if you have anaemia
- if you have low oxygen levels in the blood (hypoxaemia)
- if you have unstable blood pressure such as hypotension and hypovolemia
- if you have low thyroid function (hypothyroidism)
- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

Children

This medicine is not intended for children.

Other medicines and Isomex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines may affect your treatment with Isomex or may be affected by Isomex.

Do not use Isomex at the same time as medicines such as Viagra (sildenafil), Cialis (tadalafil) or Levitra (vardenafil), which are used in treating impotence (erectile dysfunction) or pulmonary arterial hypertension (PAH). If you take such medicines while taking Isomex, it can cause a serious drop in blood pressure that can lead to fainting or a heart attack.

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

Isomex should not be used at the same time as dihydroergotamine as it can enhance the blood pressure increasing effect of dihydroergotamine.

Medicines that expand blood vessels and lower blood pressure can affect the efficacy of Isomex.

Isomex with food, drink and alcohol

Drinking alcohol while taking Isomex can worsen a low blood pressure and make you feel dizzy or faint.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

As a precautionary measure, it is preferable to avoid the use of Isomex during pregnancy.

Pregnancy

There is limited experience of use of Isomex during pregnancy. Therefore, you should consult with your doctor before taking Isomex during pregnancy.

Breast-feeding

It is not known whether isosorbide mononitrate crosses over to human milk. A risk to the suckling child cannot be excluded. Therefore, you should not use Isomex during breast-feeding.

Driving and using machines

Isomex can cause headaches and dizziness. You should not drive, operate complex machinery or engage in any other potentially hazardous activities until you know whether this medication affects your ability to perform these activities.

Isomex contains lactose

Isomex contains a type of sugar called lactose. 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 Isomex

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

Your doctor will determine what dose is appropriate for you. A usual dose for adults is 60 mg (two tablets) of Isomex taken once daily in the morning.

Your doctor may ask you to start on a low dose so that you are less likely to get a headache when starting Isomex. Your doctor may prescribe a different dosage depending on your symptoms, your age and other medicines that you take. The dose can be increased to 120 mg daily.

Use in elderly patients

The dosage for older patients (over 65 years) is the same as for adults.

Method of administration

Swallow Isomex tablets whole. Do not break, crush or chew your tablets. Always swallow the tablets with at least half a glass of water. The tablets can be taken with or without food.

Occasionally, some users may see remnants of the tablet in their stools. This is normal and does not mean that the medicine has not been taken up in the body.

If you take more Isomex than you should

Signs of overdose may include throbbing headache, nervousness, redness, cold sweats, nausea, vomiting, dizziness, light-headedness, and rapid heart rate. If you suddenly experience any of the above, lie down with your legs slightly raised, because it can relieve the symptoms.

If you take more than you should or a child has taken the medicine accidentally, call your doctor or hospital to assess the risk and to ask for advice.

If you forget to take Isomex

Do not take a double dose to make up for the forgotten dose.

If you stop taking Isomex

Do not suddenly stop taking Isomex tablets, as this can make your angina worse. If your treatment should be ended, be sure to follow your doctor's instructions.

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 may cause side effects, although not everybody gets them.

Contact your doctor immediately if you experience any of the following side effects, as they can be serious;

- dizziness, nausea (common, may affect up to 1 in 10 people)
- fainting (rare, may affect up to 1 in 1,000 people)

Other side effects

Common (may affect up to 1 in 10 people)

- headaches that go away or subside with continued use
- low blood pressure, which can cause dizziness and nausea
- palpitations (tachycardia)

Uncommon (may affect up to 1 in 100 people)

- vomiting
- diarrhoea

Rare (may affect up to 1 in 1,000 people)

- skin rashes, itching

Very rare (may affect up to 1 in 10,000 people)

- Muscle pain (myalgia)

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 <to be completed nationally>.

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

5. How to store Isomex

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Isomex contains

- The active substance is isosorbide mononitrate. Each tablet contains 30 mg of isosorbide mononitrate.
- The other ingredients are: hypromellose, lactose monohydrate, pregelatinised starch, magnesium stearate, silica colloidal anhydrous.

What Isomex looks like and contents of the pack

Isomex tablets are white to off-white, oval prolonged-release tablets.

Isomex is packaged in bottles containing 100 tablets or in blister packs containing 28 or 98 tablets.

Not all pack sizes may be marketed.

Market Authorisation Holder and Manufacturer

RPH Pharmaceuticals AB
Lagervägen 7
136 50 Jordbro
Sweden

Manufacturer

Astrea Fontaine SAS
Rue de Prés Potets
21121 Fontaine les Dijon
France

Information provided by:

<to be completed nationally>

This medicinal product is authorised in the Member States of the EEA under the following name:

<{Name of the Member State}> <{Name of the medicinal product}> <{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}> <{Name of the Member State}> <{Name of the medicinal product}>

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