

Package leaflet: Information for the Patient

Isotard 25 mg XL[®] Tablets

Isotard 40 mg XL[®] Tablets

Isotard 50 mg XL[®] Tablets

Isotard 60 mg XL[®] 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 Isotard XL is and what it is used for
2. What you need to know before you take Isotard XL
3. How to take Isotard XL
4. Possible side effects
5. How to store Isotard XL
6. Contents of the pack and other information

1. What Isotard XL is and what it is used for

Isotard tablets contain the active substance isosorbide mononitrate (ISMN). ISMN belongs to a group of medicines called organic nitrates.

Isotard XL prolonged release tablets are used to prevent attacks of angina (chest pain). Isotard XL works by opening up blood vessels and reducing the pain.

2. What you need to know before you take Isotard XL

Do not take Isotard XL:

- if you are allergic to isosorbide mononitrate or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from increased intracranial pressure (high pressure within your skull, e.g. from a blow to your head) or cerebral haemorrhage – bleeding from a ruptured blood vessel in the brain
- if you are taking sildenafil or similar products e.g. Viagra for male erectile dysfunction
- if you are taking riociguat e.g. Adempas for pulmonary hypertension
- if you have been diagnosed with any of the following: hypertrophic obstructive cardiomyopathy (HOCM), constrictive pericarditis, cardiac tamponade or aortic/mitral valve stenosis
- if you have very low iron levels in your blood (severe anaemia)
- if you suffer from high pressure in the eye (closed angle glaucoma)

- if you have low blood pressure

Warnings and precautions

Talk to your doctor or pharmacist before taking Isotard XL:

- if you suffer from malnutrition
- if you suffer from hypothermia (body temperature which is lower than normal)
- if you are pregnant, think you might be pregnant, considering becoming pregnant or are breast feeding
- if you have severe liver or kidney disease
- if your thyroid gland is underactive or you are taking thyroxine
- if you have recently suffered from a heart attack
- if you are taking any other medication, even those you may have bought for yourself without prescription

Isotard XL should not be used for the relief of sudden (acute) attacks of angina. If you have an attack of angina you should speak to your doctor or pharmacist who may supply you with other medicines for this.

Treatment with this medicine should not be discontinued suddenly. Withdrawal from Isotard XL should be tapered gradually.

Other medicines and Isotard XL

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

Isotard XL may lower blood pressure (you may experience this as dizziness, tiredness or feeling sick) so take special care when taking other medicines that may also lower blood pressure.

Do not take Isotard XL if you are taking riociguat, e.g. Adempas for pulmonary hypertension. When taken together a fall in blood pressure can occur.

Do not take Isotard XL if you are taking sildenafil or similar products, e.g. Viagra for male erectile dysfunction. When taken together a severe and possibly dangerous fall in blood pressure can occur, which may result in collapse, unconsciousness and could be fatal.

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

Isotard XL with alcohol

You are advised NOT to drink alcohol with this medicine, as the effects of alcohol may become worse. Alcohol may also increase the side effects of this medicine and make you feel dizzy or light-headed if you stand up or move suddenly.

Pregnancy and breast-feeding

In pregnancy or when breast feeding, Isotard XL should only be used under medical supervision. 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.

Driving and using machines

Do not drive or operate machinery when taking Isotard XL if you develop low blood pressure (you may experience this as dizziness, tiredness or feeling sick) or if you have blurred vision.

Isotard XL contains:

Lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Isotard XL.

3. How to take Isotard XL

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

Very occasionally, some people see the remains of the tablet in their bowel motions. This is quite normal and does not mean the medicine has not been released.

Adults and the elderly – 1 or 2 tablets daily, ideally in the morning. Swallow Isotard XL tablets whole with water. Do not crush or chew.

Children – Isotard XL must not be given to children.

If you take more Isotard XL than you should - You should only take what your doctor recommends. If you take too many Isotard XL tablets contact your doctor or pharmacist if you can do so. If not, go to the nearest hospital casualty department immediately, taking the Isotard XL pack and remaining tablets with you.

If you have taken more Isotard XL than you should, symptoms may include nausea, vomiting, restlessness, confusion, warm flushed skin, blurred vision, headache, fainting, fast heart beats and palpitations.

If you forget to take Isotard XL - If you forget to take your tablet, take it as soon as possible and continue to take the tablets as normal. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Isotard XL – Angina is a condition which may need treatment for life, always talk to your doctor or pharmacist before stopping using Isotard XL.

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

4. Possible side effects

Like all medicines, Isotard XL can cause side effects, although not everybody gets them.

- Headaches may occur when treatment is first started but usually disappear after 1 to 2 weeks.
- Low blood pressure may occasionally occur (you may experience this as dizziness, faintness on standing, tiredness and feeling sick).
- More rarely, becoming flushed and allergic reactions (including rashes) can occur.
- Increased and decreased heart rate have also been reported.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard.

5. How to store Isotard XL

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Store in the original package.
- Do not use this medicine after the expiry date which is stated on the carton 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 protect the environment.

6. Contents of the pack and other information

What Isotard XL contains

- The active substance is isosorbide-5-mononitrate (each tablet contains 25, 40, 50 or 60 mg of the active substance)
- The other ingredients are macrogol, hypromellose, stearic acid, talc, silica colloidal anhydrous, lactose monohydrate, carnauba wax, magnesium stearate and the colourings titanium dioxide (E171) and yellow iron oxide (E172).

What Isotard XL looks like and contents of the pack

Isotard 25 mg XL, 40 mg XL and 50 mg XL tablets are round and cream in colour with 'IM25', 'IM40' and 'IM50' respectively on one side.

Isotard 60 mg XL tablets are oval and cream in colour with a score line on both sides and '60' on one side.

Isotard XL tablets are provided in packs of 28.

Marketing Authorisation Holder:

Kyowa Kirin Limited
Galabank Business Park
Galashiels
Scotland, TD1 1QH

Manufacturers:

AndersonBrecon (UK) Ltd.
Wye Valley Business Park
Hay-on-Wye
Hereford
United Kingdom, HR3 5PG

This leaflet was last revised in 05/2016