

Package leaflet: Information for the user

Isodur 25XL and 50XL Capsules

(Isosorbide-5-mononitrate)

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, pharmacist or nurse 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 side effects, talk to your doctor, pharmacist or nurse. 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 Isodur is and what it is used for
2. What you need to know before you take Isodur Capsules
3. How to take Isodur Capsules
4. Possible side effects
5. How to store Isodur Capsules
6. Contents of the pack and other information

1. What Isodur is and what it is used for

Isodur Capsules are one of a group of medicines known as nitrates. Nitrates work by widening the blood vessels in your heart to allow an increased amount of blood flow to areas which need it. They are used to help prevent an attack of angina (chest pain). This pain comes from the heart muscle and is a sign that part of it is not getting enough oxygen for the amount of work it is doing. Isodur capsules are not suitable for the relief of an angina attack.

2. What you need to know before you take Isodur Capsules

Do not take Isodur Capsules:

- if you are allergic to isosorbide-5-mononitrate, other nitrates or any of the other ingredients of this medicine (listed in section 6)
- if you are suffering a heart attack or have recently had a heart attack
- if you have been diagnosed with any of the following heart conditions: hypertrophic obstructive cardiomyopathy (HOCM), constrictive pericarditis, cardiac tamponade, low cardiac filling pressures, aortic/mitral valve stenosis
- if your blood has stopped circulating around your body properly (circulatory failure)
- if you are suffering from “shock” or vascular collapse
- if you suffer from severe anaemia (severe reduction in red blood cells)
- if you have been diagnosed with any diseases associated with raised intracranial (head) pressure
- if you are suffering from or have had a head injury (trauma)
- if you are suffering from or have had bleeding in the brain (brain haemorrhage)

- if you have an eye disease called glaucoma
- if you suffer from very low blood pressure (severe hypotension)
- if you suffer from low circulating blood volume (hypovolaemia)
- if you take sildenafil (“Viagra”) or any similar medicines used to treat erectile dysfunction (known as phosphodiesterase type-5 inhibitors)
- if you take products that contain riociguat, a medicine used in treating pulmonary hypertension

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Isodur Capsules

- if you are pregnant or there is a chance you might become pregnant
- if you are breast-feeding
- if you suffer from liver problems
- if you suffer from kidney problems
- if you are at risk of developing, or have a family history of, glaucoma
- if you suffer from an under-active thyroid gland (a condition known as hypothyroidism)
- if you suffer from hypothermia (very low body temperature)
- if you suffer from malnutrition (severe lack of food)
- if you suffer from very poor circulation
- if you have slower than normal bowel movements

If any of the above apply to you, it is important that you tell your doctor or pharmacist before taking Isodur and they will decide what to do. It may still be safe for you to take Isodur.

Children

Isodur Capsules should not be taken by children.

Other medicines and Isodur Capsules

Do not take Viagra (sildenafil – for male erectile dysfunction) or other phosphodiesterase type-5 inhibitors while you are taking Isodur. Taking these medicines while you are taking Isodur could cause a severe and possibly dangerous fall in blood pressure. This could result in collapse, unconsciousness and could be fatal. You must not stop taking Isodur to take these medicines as this will increase your chances of having an angina attack.

Do not take Isodur with products that contain riociguat, a medicine used in treating pulmonary hypertension.

It is important that you inform your doctor or pharmacist if you are taking any of the following medicines:

- Medicines that can lower your blood pressure
- Tricyclic antidepressants (used to treat depression) and neuroleptics (used to treat anxiety)
- Ergotamine used for migraine
- Sapropterin used for phenylketonuria (PKU)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Isodur Capsules with alcohol

Do not drink alcohol while taking Isodur Capsules. Alcohol could increase the effect of Isodur and lower your blood pressure too much. If this happens, you may 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. You should not use Isodur Capsules during pregnancy or while breast-feeding unless your doctor thinks it is essential.

Driving and using machines

Isodur Capsules may give you a headache, blurred vision or make you feel faint, dizzy or tired. If this happens to you, do not drive or operate machinery.

Isodur Capsules contain Sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Isodur Capsules contain Sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Isodur Capsules

If this product has been prescribed by your doctor the label on the carton will tell you how many capsules you should take and when. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one or two capsules to be taken in the morning.

This product should be taken orally (by mouth). You must swallow the capsules whole with a drink of water. The capsules must not be crushed or chewed.

Elderly patients or patients with low blood pressure, kidney or liver disease may be advised to take a lower dose.

Do not use Isodur to treat an actual angina attack. Your doctor will give you a different medicine such as GTN (glyceryl trinitrate) spray or tablet for this.

Use in children

This medicine should not be given to children.

If you take more Isodur Capsules than you should

If you take too many capsules, contact your nearest hospital casualty department or doctor immediately. Take this leaflet and any remaining capsules with you.

Too much Isodur may cause your blood pressure to fall too low, making you feel sick, faint and dizzy. A very large overdose could cause a coma or collapse and require immediate resuscitation.

If you forget to take Isodur Capsules

If you forget to take your capsule(s), take your recommended dose as soon as you remember and then carry on as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking Isodur Capsules

Do not stop taking Isodur Capsules without consulting your doctor. Stopping your medicine suddenly may lead to your condition getting worse.

If you have an angina attack (chest pain) despite taking Isodur Capsules, your doctor will supply you with another medicine for this. Do not stop taking your Isodur Capsules.

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

4. Possible side effects

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

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

- Fainting or collapse

Very common side effects (may affect more than 1 in 10 people):

- Headaches (may occur when this treatment is first started, but these usually disappear after 1-2 weeks)

Common side effects (may affect up to 1 in 10 people):

- Dizziness
- Sleepiness
- Feeling weak
- Fast heartbeat
- Lowering of blood pressure (e.g. feeling dizzy or light-headed) when standing up

They may occur for the first few days of treatment or after your dosage has been increased.

Uncommon side effects (may affect up to 1 in 100 people):

- Fainting or collapse
- Feeling sick or being sick
- Skin rashes
- Flushing (when your face, ears, neck and, occasionally, your upper chest, become red in colour)
- Increase in chest pain/angina

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

- Heartburn

Other side effects (frequency cannot be estimated from the available data):

- Red or scaly skin (exfoliative dermatitis)

- Low blood pressure
- Swelling of the skin
- Stomach upsets
- Tiredness
- Uneven heartbeat
- Looking pale
- Excessive sweating
- Restlessness

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 website: 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 Isodur Capsules

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 and blister foil. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the packaging or any of the capsules are damaged.

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 Isodur Capsules contain

The active substance is called isosorbide-5-mononitrate.

The other ingredients are sucrose, maize starch, shellac, povidone, ethylcellulose and talc.

The capsule shells of Isodur 25XL are made of gelatin and contain the following colourings: titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172).

The capsule shells of Isodur 50XL are made of gelatin and contain the following colourings: titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172) and erythrosine (E127).

The ink on the capsule shells contains: shellac, propylene glycol, strong ammonia solution, potassium hydroxide, titanium dioxide (E171), povidone and sodium hydroxide.

Isodur Capsules come in two different strengths of capsule:

- Isodur 25XL Capsules, which contain 25mg of isosorbide-5-mononitrate per prolonged-release capsule.
- Isodur 50XL Capsules, which contain 50mg of isosorbide-5-mononitrate per prolonged-release capsule.

What Isodur capsules look like and the contents of the pack

- Isodur 25XL Capsules are hard gelatin capsules, which have a brown cap and a white body, with “ISM 25” overprinted in white ink.
- Isodur 50XL Capsules are hard gelatin capsules, which have a brown cap and a red body, with “ISM 50” overprinted in white ink.

Isodur 25XL and 50XL Capsules are packaged in calendar/blister packs containing 28 capsules.

Marketing Authorisation Holder

Galen Limited
Seago Industrial Estate
Craigavon
BT63 5UA
UK

Manufacturer

Almac Pharma Services Limited
Almac House
20 Seago Industrial Estate
Craigavon
BT63 5QD
UK

AndersonBrecon (UK) Limited
Units 2-7
Wye Valley Business Park
Brecon Road
Hay-on-Wye
Hereford
HR3 5PG
UK

This leaflet was last revised in 08/2020.