

Elantan® LA
25mg Prolonged Release Capsules, hard
(isosorbide mononitrate)

PATIENT INFORMATION LEAFLET

Your medicine is available using the above name but will be referred to as Elantan LA 25 throughout this leaflet.

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Elantan LA 25 is for
2. Before you take Elantan LA 25
3. How to take Elantan LA 25
4. Possible side effects
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1. What Elantan LA 25 is for

Elantan LA 25 belongs to a group of medicines called organic nitrates. Organic nitrates work by widening the blood vessels in your heart to allow an increased amount of blood to flow to areas which need it.

Elantan LA 25 is used to prevent angina pectoris. Angina usually feels like a tight pain in the chest, neck or arm area. The 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.

2. Before you take Elantan LA 25

Do not take Elantan LA 25 if:

- You are allergic to isosorbide mononitrate, other nitrates or any of the other ingredients of Elantan LA 25 (see section 6)
- You suffer from anaemia
- You have had a heart attack (myocardial infarction)
- You have had a brain haemorrhage (bleeding)
- You have had a head injury (trauma)
- You have a low blood volume (hypovolaemia)
- You have very low blood pressure
- You are suffering from "shock" as the blood has stopped circulating properly around your body (circulatory failure)
- You take sildenafil tadalafil or vardenafil (medicines to treat erectile dysfunction and/or pulmonary hypertension) or any other phosphodiesterase inhibitor.
- You have an eye disease called glaucoma

- 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 and diseases associated with raised intra-cranial (head) pressure.

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

Check with your doctor before taking Elantan LA 25 if:

- You have an underactive thyroid gland
- You are malnourished (severely underfed)
- You have liver or kidney disease
- You suffer from hypothermia (a very low body temperature)
- You suffer from very poor circulation

Taking other Medicines

- **Do not take Elantan LA 25 with phosphodiesterase inhibitors such as Sildenafil, Alprostadil, Tadalafil and Vardenafil used for impotence. Using Elantan LA 25 with these medicines could cause your blood pressure to fall to a dangerously low level. You must not stop taking Elantan LA 25 to take these medicines as this will increase your chances of having an angina attack.**

Tell your doctor if you are taking any of the following medicines:

- Medicines to lower your blood pressure such as beta blockers (atenolol, propranolol), calcium channel blockers (nifedipine, diltiazem), vasodilators (glycerol trinitrate, methyl dopa), angiotensin receptor blockers (olmesartan medoxomil, candesartan cilexetil)
- Tricyclic antidepressants such as amitriptyline, clomipramine (used to treat depression)
- Neuroleptics to treat psychosis (delusions, hallucinations and/or disordered thought) such as phenothiazines (fluphenazine) or butyrophenones (haloperidol)
- Ergotamine used for migraine.
- Aldesleukin (for kidney cancer)
- Any other medicine, including medicines obtained without a prescription.

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

Using Elantan LA 25 with food, drink and alcohol

Do not drink alcohol. It could increase the effect of Elantan LA 25 and lower your blood pressure too much. If this happens, you may feel dizzy or faint.

Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking Elantan LA 25. Your doctor will decide whether you should take this medicine

Driving and using machines

Elantan LA 25 may give you a headache, blurred vision or make you feel dizzy or tired. If this happens to you, do not drive or operate machinery.

Warnings about the ingredients

This medicine contains lactose and 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

3. How to take Elantan LA 25

Always take Elantan LA 25 exactly as your doctor has told you.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Adults

- The usual adult dose is one capsule once a day, in the morning.
- If your doctor increases your dose to two capsules, you should take them together in the morning.
- To remove the capsule from the packaging, carefully push one end of the capsule through the foil. If you push in the middle you may damage the capsule.
- Swallow the capsule whole with a drink of water after meals.
- If you do not take the dose as prescribed by your doctor, you may develop a tolerance to Elantan.

Do not use Elantan LA 25 to treat an actual angina attack. Your doctor will give you a different medicine such as a GTN (glyceryl trinitrate) spray or tablet for this.

Children

This medicine is not suitable for children.

If you take more Elantan LA 25 than you should

Do not take more Elantan LA 25 than you should. If you accidentally take too much, immediately contact the nearest hospital casualty department or your doctor.

Too much Elantan LA 25 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 Elantan LA 25

Do not take a double dose to make up for a missed dose. Take your next dose at the usual time.

If you stop taking Elantan LA 25

Do not stop taking Elantan LA 25 without first talking to your doctor. You should keep taking your medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the tablets your condition may get worse.

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

4. Possible side effects

Like all medicines Elantan LA 25 can cause side effects, although not everybody gets them.

Seek immediate help if you are having an allergic reaction. This includes any of the following symptoms:

- Difficulty in breathing
- Swelling of your eyelids, face or lips
- Rash or itching especially those covering your whole body
- Collapse
- Fainting
- Exfoliative dermatitis (Serious illness with blistering of the skin, mouth, eyes and genitals)

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

- Throbbing headache at the start of treatment.

Usually they disappear after a few days.

Common side effects (affects less than 1 in 10 people):

- Light headed on standing upright
- Dizziness
- Tiredness
- Feeling weak
- Fast heartbeat
- Drowsiness

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

Uncommon side effects (affects less than 1 in 100 people):

- Fainting or collapse
- Feeling sick or being sick
- Skin rashes
- Looking pale
- Excessive sweating
- Restlessness
- Worsening angina (tight pain in the chest, neck or arm area)
- Flushing.

Very rare side effects (affects less than 1 in 10,000 people):

- Heartburn
- Red or scaly skin (exfoliative dermatitis).

Very slow heart rate has been reported with use of nitrates.

If you experience any symptoms of shock or collapse after first dose, please contact your doctor immediately.

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.

5. How to store Elantan LA 25

- Do not use this medicine after the expiry date which is stated on the carton and blister foil after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Keep this medicine in a safe place, out of the reach and sight of children.
- If your capsules appear to be discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.
- If your doctor decides to stop treatment, return any left over medicine to a pharmacist for safe disposal. Only keep it if the doctor tells you to.

6. Further information

What Elantan LA 25 contains

The name of your medicine is Elantan LA 25mg Prolonged Release Capsules, hard.

Each capsule contains 25mg of the active ingredient isosorbide mononitrate.

The capsules also contain gelatin, lactose monohydrate, ethyl cellulose, talc, hypromellose, macrogol 20,000, sucrose, corn starch and colours titanium dioxide (E171) and iron oxide red and black (E172).

What Elantan LA 25 looks like

Elantan are a hard capsule with brown cap and white body, containing white to off-white pellets.

Elantan are available in blister packs containing 28 prolonged release capsules.

Manufacturer

This product is manufactured by: UCB Pharma GmbH, Alfred Nobel Strasse 10, D-40789, Monheim, Germany or Aesica Pharmaceuticals GmbH, Alfred Nobel Strasse 10, D-40789, Monheim, Germany

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd, Santry, Dublin 9.

PPA No: 1151/78/2

Leaflet revision and issue date (ref): 03.09.12

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