

Package leaflet: Information for the patient

Elantan® LA 50mg Prolonged Release Capsules, hard (isosorbide mononitrate)

Your medicine is available using the above name but will be referred to as Elantan LA 50 throughout this leaflet.

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:

- What Elantan LA 50 is and what it is used for
- What you need to know before you take Elantan LA 50
- How to take Elantan LA 50
- Possible side effects
- How to store Elantan LA 50
- Contents of the pack and other information

1. What Elantan LA 50 is and what it is used for

Elantan LA 50 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 50 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. What you need to know before you take Elantan LA 50

Do not take Elantan LA 50:

- if you are allergic to isosorbide mononitrate, other nitrates or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from severe anaemia
- if you have had a heart attack (myocardial infarction)
- if you have had a brain haemorrhage (bleeding)
- if you have had a head injury (trauma)
- if you have severely low blood volume (hypovolaemia)
- if you have severe low blood pressure

- if you are suffering from "shock" as the blood has stopped circulating properly around your body (circulatory failure)
- if you take sildenafil, tadalafil or vardenafil (medicines to treat erectile dysfunction and/or pulmonary hypertension) or any other phosphodiesterase inhibitor
- if you have an eye disease called glaucoma
- 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 and diseases associated with raised intra-cranial (head) pressure
- 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 or pharmacist before taking Elantan LA 50:

- if you have an underactive thyroid gland
- if you are malnourished (severely underfed)
- if you have liver or kidney disease
- if you suffer from hypothermia (a very low body temperature)
- if you suffer from very poor circulation
- if you have abnormally low level of oxygen in the blood and impaired gas exchange due to lung disease or ischaemic heart failure.

Other medicines and Elantan LA 50

- Do not take Elantan LA 50 with phosphodiesterase inhibitors such as Sildenafil, Alprostadil, Tadalafil and Vardenafil used for impotence. Using Elantan LA 50 with these medicines could cause your blood pressure to fall to a dangerously low level. You must not stop taking Elantan LA 50 to take these medicines as this will increase your chances of having an angina attack.**
- Do not take Elantan LA 50 with products that contain riociguat.**

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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), ACE-inhibitors, angiotensin receptor blockers (olmesartan medoxomil, candesartan cilexetil), monoamine oxidase inhibitors
- 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)
- Sapropterin containing medicines for the treatment of hyperphenylalaninemia (HPA)
- Any other medicine, including medicines obtained without a prescription.

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

Elantan LA 50 with alcohol

Do not drink alcohol. It could increase the effect of Elantan LA 50 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 50. Your doctor will decide whether you should take this medicine.

Driving and using machines

Elantan LA 50 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.

Elantan LA 50 contains lactose monohydrate and sucrose

This medicine contains lactose and sucrose. If you have an intolerance to some sugars, tell your doctor before taking this medicine.

3. How to take Elantan LA 50

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

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 50 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.

Use in children

This medicine is not suitable for children.

If you take more Elantan LA 50 than you should

Do not take more Elantan LA 50 than you should. If you accidentally take too much, immediately contact the nearest hospital casualty department or your doctor.

Too much Elantan LA 50 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 50

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

If you stop taking Elantan LA 50

Do not stop taking Elantan LA 50 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 50 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):

- Headache

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

- Light headed on standing upright
- Dizziness
- Sleepiness
- 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

Other side effects

- Red or scaly skin (exfoliative dermatitis)
- Low blood pressure
- Swelling of the skin

You may also suffer with increased chest pain due to a lack of oxygen to the heart muscle and areas around the chest.

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.

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 directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie e-mail: medsafty@hpra.ie

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

5. How to store Elantan LA 50

- **Keep this medicine in safe place 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 after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- If your doctor decides to stop treatment, return any left-over medicine to a pharmacist for safe disposal. Only keep it if your doctor tells you to.
- If your capsules appear to be discoloured, damaged or show any signs of deterioration or damage please return these to your pharmacist who will advise you further.
- 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 Elantan LA 50 contains

Each capsule contains 50mg of isosorbide mononitrate as the active ingredient.

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

What Elantan LA 50 looks like and contents of the pack

Elantan LA 50 are a size 3 hard gelatin opaque capsule with a brown capsule cap and flesh coloured body, containing white to beige odourless pellets.

Elantan LA 50 are available in blister packs containing 28 prolonged release capsules.

Manufacturer

Manufacturer: Aesica Pharmaceuticals GmbH, Alfred Nobel Strasse 10, D-40789, Monheim, Germany.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

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(Regulatory)