

Package leaflet: Information for the user

Elantan LA 50 mg prolonged release capsules 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 Elantan LA is and what it is used for
2. What you need to know before you take Elantan LA
3. How to take Elantan LA
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1. What Elantan LA is and what it is used for

Elantan LA 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 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

Do not take Elantan LA if:

- You are allergic to isosorbide mononitrate, other nitrates or any of the other ingredients of this medicine (listed in section 6)
- You have an acute heart attack episode (acute myocardial infarction)
- Your blood is not circulating around your body properly (circulatory failure)
- You are suffering from “shock” or collapse of the blood vessels
- You are suffering from any of the following heart conditions:
 - hereditary thickened heart muscle (hypertrophic obstructive cardiomyopathy [HOCM])
 - inflammation of the protective sac surrounding the heart (constrictive pericarditis)
 - build-up of fluid between the heart and its protective sac (cardiac tamponade)
 - low heart (cardiac) filling pressures
 - narrowing of the valves in the heart (aortic/mitral valve stenosis)
 - diseases associated with raised pressure inside the head (intra-cranial pressure)
- You suffer from reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (severe anaemia)
- You have bleeding in the brain (brain haemorrhage)
- You have a head injury (trauma)
- You have severely low blood volume (hypovolaemia)
- You have severely low blood pressure

- You take sildenafil (Viagra) or any other phosphodiesterase-5 (PDE-5) inhibitor drugs used for erectile dysfunction such as tadalafil and vardenafil
- You have an eye disease called closed angle glaucoma
- 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

Elantan LA is not suitable for the treatment of suddenly occurring chest pain (e.g. acute angina pectoris attack). In the event of an angina attack, an under-the-tongue (sublingual) treatment, such as GTN (glyceryl trinitrate) spray or tablet should be used instead of Elantan LA.

Talk to your doctor or pharmacist before taking Elantan LA:

- if you have a recent history of heart attack, or the left side of your heart is not working properly. It is important that blood pressure does not fall too low
- if you suffer from low blood pressure (hypotension) as nitrates can further decrease it, or cause low blood pressure upon standing
- if you have an underactive thyroid gland
- if you are severely underfed (malnourished)
- if you have severe liver or severe kidney disease
- if you suffer from a very low body temperature (hypothermia)
- if you suffer from very poor blood circulation
- if you have slower than normal bowel movements
- if you have an abnormally low level of oxygen in the blood and impaired gas exchange due to lung disease or ischaemic heart failure
- if you are lactose intolerant, as Elantan LA contains lactose.

Organic nitrates have been shown to stop working or become less effective if they are taken continuously at high doses. It is important to closely follow the dosing instructions to avoid this.

Treatment with Elantan LA should not be stopped suddenly. Talk to your doctor before stopping Elantan LA (see section 3).

During treatment with Elantan LA you must not take medicinal products that contain PDE-5 inhibitors (e.g. sildenafil, tadalafil, vardenafil) for the treatment of erectile dysfunction (see section Other medicines and Elantan LA).

During treatment with Elantan LA, drinking alcohol should be avoided because alcohol can enhance the blood-pressure-lowering effect of Elantan LA (see section Elantan LA with food, drink and alcohol).

Other medicines and Elantan LA

- **Do not take Elantan LA with PDE-5 inhibitors such as sildenafil (Viagra) used for erectile dysfunction. Using Elantan LA with these medicines could cause your blood pressure to fall to a dangerously low level. You must not stop taking Elantan LA to take PDE-5 inhibitors as this will increase your chances of having an angina attack.**
- Do not take Elantan LA with products that contain riociguat, a medicine used in treating pulmonary hypertension.

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, calcium channel blockers, vasodilators, alprostadil, aldesleukin, angiotensin II receptor antagonists
- Monoamine oxidase inhibitors (used to treat depression)

- Tricyclic antidepressants (used to treat depression) and neuroleptics (used to treat anxiety)
- Ergotamine used for migraine
- Sapropterin used for phenylketonuria (PKU)
- Any other medicine, including medicines obtained without a prescription.

Alcohol may also potentiate the lowering of blood pressure effect of nitrates.

Elantan LA with food, drink and alcohol

Do not drink alcohol. It could increase the effect of Elantan LA 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.

Driving and using machines

If you have blurred vision or feel dizzy or tired while taking Elantan LA, do not drive or operate machinery. This effect may be increased by alcohol use (see Elantan LA with food, drink and alcohol).

Elantan LA 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

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.

Do not use Elantan LA 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.

A reduced effect during use of this type of medicine has occurred in some patients, so intermittent treatment may be more suitable. Your doctor will decide the most suitable dosing for you.

Treatment with Elantan LA should not be stopped suddenly; the dosage and frequency should be gradually decreased. Talk to your doctor before stopping Elantan LA.

Use in children

This medicine is not suitable for children.

If you take more Elantan LA than you should

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

Symptoms of taking too much Elantan LA may include a decrease in blood pressure, paleness, diarrhoea, sweating, weak pulse, rapid heartbeat, headache, weakness, feeling sick, vomiting, feeling faint or dizzy.

Taking too much Elantan LA may cause a change in red blood cells (methaemoglobinemia), potentially resulting in bluish discolouration of the skin, which may be followed by rapid breathing, anxiety, unconsciousness and heart attack. This is a possible reaction to Elantan LA and similar medicines, due to the way they are changed when they are absorbed into the body.

If you have any of these symptoms, lie on your back and position your feet so that they are higher than your head. Contact a doctor or a hospital immediately. The doctor can decide on the actions that must be taken according to the severity of the overdose and the nature of the discomfort. Take this package leaflet or the Elantan LA package with you so that the doctor knows which medicine you have taken.

A very large overdose could cause an increase in the pressure in the head, a coma or collapse and require immediate resuscitation.

If you forget to take Elantan LA

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

Do not stop taking Elantan LA 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 medication your condition may get worse.

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 can cause side effects, although not everybody gets them.

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

- Fainting or collapse
- Severe decrease in blood pressure (hypotension), with nausea, vomiting, restlessness, looking pale and excessive sweating, which have been reported during treatment with organic nitrates.
- Increased chest pain, which may occur due to a lack of oxygen to the heart muscle and areas around the chest.

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

- Headache

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

- Dizziness
- Sleepiness
- Feeling weak
- Fast heartbeat
- Lowering of blood pressure when standing up.

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
- Flushing
- Increase in chest pain/angina
- Blood vessel collapse (possibly together with slow abnormal heart rate and sudden loss of consciousness).

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

- Heartburn

Other side effects (frequency unknown):

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

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 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 Elantan LA

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.

Do not store above 30°C.

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 contains**

- The active substance is isosorbide mononitrate. Each capsule contains 50 mg of isosorbide mononitrate.
- The other ingredients are lactose monohydrate, purified talc, ethyl cellulose, macrogol 20,000, hydroxypropyl cellulose, sucrose, corn starch, gelatin, titanium dioxide, iron oxide red (E172), iron oxide black (E172).

What Elantan LA looks like and contents of the pack

Elantan LA 50 mg is a hard capsule with brown opaque cap and flesh opaque body, containing white to off-white pellets. They come in blister packs of 28 capsules.

Marketing Authorisation Holder

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If this leaflet is difficult to see or read or you would like it in a different format, please contact

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