

## Package Leaflet: Information for the patient

### Elantan<sup>®</sup> 20mg 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

The name of your medicine is Elantan 20mg tablets but will be referred to as Elantan throughout this leaflet.

#### In this leaflet:

1. What Elantan is and what it is used for
2. What you need to know before you take Elantan
3. How to take Elantan
4. Possible side effects
5. How to store Elantan
6. Contents of the pack and other information

#### 1. What Elantan is and what it is used for

Elantan 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 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.

Elantan can also be used to treat congestive heart failure. Heart failure can happen when the heart muscle is not strong enough to pump the blood around the body. It may cause problems with breathing and swelling of the legs.

#### 2. What you need to know before you take Elantan

##### Do not take Elantan if:

- You are allergic to isosorbide mononitrate, other nitrates or any of the other ingredients of Elantan (see section 6)
- You suffer from severe anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- You have had a heart attack (myocardial infarction)
- You have had a brain haemorrhage (bleeding)
- You have had a head injury (trauma)
- You have severely low blood volume (hypovolaemia)
- You have severely low blood pressure
- Your blood has stopped circulating around your body properly (circulatory failure)
- You take Sildenafil ('Viagra') or any other phosphodiesterase inhibitor
- You are suffering from 'shock' or vascular collapse
- 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
- 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.

#### Check with your doctor before taking Elantan 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
- You have slower than normal bowel movements

#### Taking other Medicines

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

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

- Medicines to 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)
- Any other medicine, including medicines obtained without a prescription.

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

#### Using Elantan with food and drink

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

Your doctor will decide whether you should take this medicine.

#### Driving and using machines

Elantan 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 in Elantan

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

#### 3. How to take Elantan

Always take Elantan 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 tablet two or three times a day
- Your doctor will tell you when you should take your tablets. You will need to have a period of time (usually when you are sleeping) when no tablets are taken. This is called a 'nitrate low' period and is needed to make sure your medicine remains effective
- Swallow the tablets whole with a drink of water
- Your doctor may increase your dose, up to a maximum of 120mg per day.

**Do not use Elantan 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 than you should

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

Too many Elantan 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

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

Do not stop taking Elantan 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 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** (affects more than 1 in 10 people):

- Headaches

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

- Dizziness
- Sleepiness
- Feeling weak
- Fast heart beat
- 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
- Looking pale
- Flushing
- Excessive sweating
- Restlessness
- Increase in chest pain/angina.

**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.

### 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Elantan

Keep out of the sight and reach of children.

This medicine does not require any special storage condition.

Do not take the tablets after the expiry date which is stated on the carton and blister label after 'Exp'. The expiry date refers to the last day of that month.

If the tablets become discoloured or show any signs of deterioration, seek the advice of your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What Elantan contains

The active ingredient in Elantan is isosorbide mononitrate. Each tablet contains 20mg isosorbide mononitrate.

The other ingredients are talc, lactose monohydrate, colloidal anhydrous silica, potato starch, microcrystalline cellulose and aluminium stearate.

### What Elantan looks like and contents of the pack

Elantan is white, round tablet with a scoreline on one side and plain on the other, marked with 'E' on top and '20' on the bottom of the scoreline.

Elantan is supplied in blister packs containing 50 tablets.

**Manufactured by:** Aesica Pharmaceuticals GmbH, Alfred Nobel Strasse 10-40789, Monheim, Germany.

### Procured from within the EU and repackaged by the Product Licence holder:

B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Elantan® 20mg tablets, PL 18799/2357**

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Leaflet date: 07.07.2016

Elantan is a registered trademark of UCB Pharma Ltd.

## Package Leaflet: Information for the patient

# Isosorbide mononitrate 20mg tablets

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The name of your medicine is Isosorbide mononitrate 20mg tablets but will be referred to as Isosorbide mononitrate throughout this leaflet.

### In this leaflet:

1. What Isosorbide mononitrate is and what it is used for
2. What you need to know before you take Isosorbide mononitrate
3. How to take Isosorbide mononitrate
4. Possible side effects
5. How to store Isosorbide mononitrate
6. Contents of the pack and other information

## 1. What Isosorbide mononitrate is and what it is used for

Isosorbide mononitrate 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.

Isosorbide mononitrate 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.

Isosorbide mononitrate can also be used to treat congestive heart failure. Heart failure can happen when the heart muscle is not strong enough to pump the blood around the body. It may cause problems with breathing and swelling of the legs.

## 2. What you need to know before you take Isosorbide mononitrate

### Do not take Isosorbide mononitrate if:

- You are allergic to isosorbide mononitrate, other nitrates or any of the other ingredients of Isosorbide mononitrate (see section 6)
- You suffer from severe anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- You have had a heart attack (myocardial infarction)
- You have had a brain haemorrhage (bleeding)
- You have had a head injury (trauma)
- You have severely low blood volume (hypovolaemia)
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### Taking other Medicines

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

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### Driving and using machines

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### Warnings about the ingredients in Isosorbide mononitrate

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## 3. How to take Isosorbide mononitrate

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