

Package leaflet: Information for the user

Zevona XL 30 mg prolonged-release 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 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 Zevona XL tablets are and what are they used for
2. What you need to know before you take Zevona XL tablets
3. How to take Zevona XL tablets
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1. What Zevona XL tablets are and what they are used for

The name of your medicine is Zevona XL 30 mg prolonged-release tablets, referred to as Zevona XL tablets throughout this leaflet. Zevona XL tablets contain the active ingredient isosorbide mononitrate, which belongs to a group of medicines called nitrates.

- It is used to prevent chest pain (angina)
- It works by making the blood vessels relax and widen. This makes it easier for the heart to pump blood around the body.

The tablets are made so that they release the medicine slowly over a number of hours.

2. What you need to know before you take Zevona XL tablets

Do not take Zevona XL tablets

- if you are allergic to isosorbide mononitrate or any of the other ingredients of this medicine (listed in section 6)
- if you have ever had a stroke
- if you have very low blood pressure
- if you have severe anaemia
- if you have a heart problem called "cardiomyopathy" or "pericarditis" or you have narrow heart valves
- if you are taking sildenafil or similar medicines called Phosphodiesterase Type 5 Inhibitors (used for male impotence). See section "Other medicines and Zevona XL tablets".

Do not take Zevona XL tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Zevona XL tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zevona XL tablets if:

- You have ever had any serious damage to your heart, such as a heart attack or operation.

If any of the above apply to you, or you are not sure, talk to your doctor or pharmacist before taking Zevona XL tablets.

Other medicines and Zevona XL tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Zevona XL tablets can affect the way some medicines work and some medicines can have an effect on Zevona XL tablets.

Do not take Zevona XL tablets if you are taking the following medicines:

- Sildenafil or similar medicines called Phosphodiesterase Type 5 Inhibitors, (used for male impotence).

Do not take Zevona XL tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Zevona XL tablets.

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

You may feel dizzy after taking Zevona XL tablets. If this happens, do not drive or use any tools or machines.

Zevona XL tablets contain lactose

Zevona XL tablets contain a type of sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Zevona XL tablets

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

Taking this medicine

- Swallow the tablets whole
- Take the tablets with half a glass of water
- Do not crush or chew the tablets

How much to take

- The recommended dose is 60 mg (two tablets) or 120mg (4 tablets) a day
- Take the medicine in the morning
- Your doctor may ask you to start on a low dose so that you are less likely to have a reaction to starting Zevona XL tablets.

You must not take Zevona XL tablets for a sudden attack of angina. If you have a sudden attack, take a glyceryl trinitrate tablet (follow the instructions given on the label).

Very occasionally, some users may see the remnants of the tablet in their bowel motions. This is quite normal and does not mean that the medicine has not been released.

Use in children

Do not give these tablets to children.

If you take more Zevona XL tablets than you should

If you take more Zevona XL tablets than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you to the tablets can be identified.

If you forget to take Zevona XL tablets

- If you forget a dose take it as soon as you remember it. However if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

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 may cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Headaches.
- Feeling sick (nausea).
- Feeling dizzy.

The above problems usually disappear with time.

Other possible side effects

Common (may affect up to 1 in 10 people)

- low blood pressure. This may make you feel faint or dizzy
- faster heartbeat
- headache
- feeling dizzy
- feeling sick (nausea)



Uncommon (may affect up to 1 in 100 people)

- being sick (vomiting)
- diarrhoea

Rare (may affect up to 1 in 1,000 people)

- fainting
- rash
- itchy skin

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

- pain in muscles

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 at: 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 Zevona XL tablets

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.

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 Zevona XL tablets contain

- The active substance is isosorbide mononitrate. Each tablet contains 30 mg of isosorbide mononitrate.
- The other ingredients are: hypromellose, lactose monohydrate, pregelatinised starch, magnesium stearate, silica colloidal anhydrous.

What Zevona XL tablets looks like and contents of the pack

Zevona XL tablets are white to off-white, oval prolonged-release tablets. Zevona XL tablets are packaged blister packs containing 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Zentiva Pharma UK Limited
12 New Fetter Lane
London
EC4A 1JP
United Kingdom

Manufacturer:

Astrea Fontaine SAS
Rue de Prés Potets
21121 Fontaine les Dijon
France

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Other sources of information

For information on large print, Braille or audio CD call emc accessibility on 0800 198 5000

