

Package leaflet: Information for the user

Xismox® 60 XL Prolonged Release Tablets (Isosorbide Mononitrate)

Read all of this leaflet carefully before you start taking Xismox 60 XL because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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. You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

1. What Xismox 60 XL is and what it is used for
2. What you need to know before you take Xismox 60 XL
3. How to take Xismox 60 XL
4. Possible side effects
5. How to store Xismox 60 XL
6. Contents of the pack and other information

1. WHAT XISMOX 60 XL IS AND WHAT IT IS USED FOR

Xismox 60 XL Prolonged Release Tablets (referred to as Xismox 60 XL throughout this leaflet) contains a medicine called Isosorbide Mononitrate. This belongs to a group of medicines called 'nitrates'.

- It is used to prevent chest pain (angina). Angina is a crushing pain or tightness in the chest, although the pain may also be felt in the neck or arm. The pain happens when the muscle in the heart does not receive enough oxygen for the work it has to do. Xismox 60 XL works by improving the supply of blood and oxygen to the heart muscle. The tablets will release your medicine slowly and will treat your condition throughout the day.
- It works by making the blood vessels relaxed 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 XISMOX 60 XL

Do not take XISMOX 60 XL:

DO NOT use these tablets to treat sudden chest pain (acute angina). **Instead seek immediate medical attention.** These tablets work too slowly to treat this and are only used to prevent symptoms of angina from happening.

- If you are allergic (hypersensitive) to isosorbide mononitrate or any of the other ingredients of this medicine (listed in Section 6: Further information).
- 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 the section "Other medicines and Xismox 60 XL".

Do not take Xismox 60 XL if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Xismox 60 XL.

WARNINGS AND PRECAUTIONS

Talk to your doctor or pharmacist before taking Xismox 60 XL:

- If you have ever had any serious damage to your heart, such as a heart attack or operation.
- If you have labile (unsteady) circulation. Speak with your doctor as treatment may be started with a 30mg dose.
- If you suffer from an under-active thyroid gland.
- If you have hypoxaemia (low oxygen level in your blood, due to lung disease for example).
- If you suffer from hypothermia (symptoms include shiver, abnormal drowsiness, confusion).
- If you suffer from malnutrition.
- If you suffer from severe liver or renal disease.

If any of the above apply to you, or you are not sure, talk to your doctor or pharmacist before taking Xismox 60 XL.

Other medicines and Xismox 60 XL

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Xismox 60 XL can affect the way some medicines work and some medicines can have an effect on Xismox 60 XL.

Do not take Xismox 60 XL if you are taking the following medicines:

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

If you take one of these drugs for erectile dysfunction, taking nitrate preparations such as Xismox 60 XL as well can cause a severe and possible dangerous fall in blood pressure. This could result in fainting, or even worse, in a heart attack.

Do not take Xismox 60 XL if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Xismox 60 XL.

The following medicines may interfere with the way Xismox 60 XL works:

- noradrenaline (norepinephrine) (used to treat sharp and severe drop in blood pressure)
- acetylcholine (used to shrink the pupil of the eye during cataract surgery and other types of eye surgery)
- histamine (used mostly as a diagnostic agent in some medical conditions)
- any drugs used to treat high blood pressure (e.g. beta-blockers, calcium channel blockers, vasodilators, angiotensin II receptor antagonists, ACE inhibitors).

Taking Xismox 60 XL with alcohol

Avoid drinking alcohol while taking Xismox 60 XL, as the side-effect of low blood pressure may be worse than normal and you may feel dizzy or faint.

Pregnancy, breast-feeding and fertility

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 get a headache or feel dizzy after taking Xismox 60 XL.

If this happens, do not drive or use any tools or machines.



XISMOX 60 XL contains lactose and sucrose

If you have been told by your doctor that you have intolerance to one or more sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE XISMOX 60 XL

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

Taking this medicine

- The tablets can be divided into equal doses.
- Take the tablets with half a glass of water.
- Do not crush or chew the tablets.

How much to take

- The recommended dose is one or two tablets a day.
- Take the medicine in the morning.
- Your doctor may ask you to start with a low dose so that you are less likely to have a reaction to starting Xismox 60 XL.

You must not take Xismox 60 XL for a sudden attack of angina. If you have a sudden attack, take a glycerol trinitrate tablet (follow the instructions given on the label).

Use in Children

Do not give these tablets to children.

Elderly

If you are an elderly person, your dosage should be the same as above, unless you suffer from low blood pressure or have a severe liver or kidney disorder – in any case you should follow your doctor's instructions. If you are already taking medication such as beta-blockers or calcium channel blockers, let your doctor or pharmacist know, as he/she may need to adjust your dose of Xismox 60 XL or existing treatment (see Section 2 "Other medicines and Xismox 60 XL").

If you take more XISMOX 60 XL than you should

If you take more Xismox 60 XL than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you so the tablets can be identified.

Symptoms of an overdose can include: pounding headache, excitation, cold sweat, nausea (feeling sick), vomiting (being sick), vertigo (a feeling of dizziness or "spinning"), fainting, racing pulse.

If you forget to take XISMOX 60 XL

- If you forget a dose, take it as soon as you remember. 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 further questions on the use of this medicine, ask your doctor or pharmacist.

If you stop taking XISMOX 60 XL

Do not suddenly stop taking XISMOX 60 XL tablets, as this could make your angina worse. If your treatment is to be stopped this should be done gradually. Be sure to follow your doctor's instructions. Ask your doctor or pharmacist any further questions you may have.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can 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 and dizzy especially when getting up from lying or sitting position, but this usually disappears in time on continued use.
- Tachycardia (fast heart beat).
- 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 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 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 XISMOX 60 XL

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not transfer them to another container. 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 throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What XISMOX 60 XL contains**

- The active substance is isosorbide mononitrate. Each tablet contains 60mg of the active substance.
- The other ingredients are Hydroxypropyl methylcellulose 2208, lactose, compressible sugar (composed of sucrose and maltodextrin), magnesium stearate, silica colloidal anhydrous, ferric oxide yellow E-172.

What XISMOX 60 XL looks like and contents of the pack

XISMOX 60 XL tablets are light yellow, biconvex, oval-shaped, scored on both sides and marked "DX 31" on one side.

XISMOX 60 XL is available in packs of 28 tablets in foil blister strips (2 blister packs of 14 tablets); 30 tablets in foil blister strips (3 blister packs of 10 tablets). Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Dexcel@-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire NN11 8PB, UK.

Manufactured for:

Genus Pharmaceuticals, Linthwaite, Huddersfield, HD7 5QH, UK.

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