**PATIENT INFORMATION LEAFLET**

**XISMOM® 60 XL PROLONGED RELEASE TABLETS**

*(isosorbide Mononitrate)*

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

This medicine is available without prescription. However, you still need to use XISMOM 60 XL Prolonged Release Tablets carefully to get the best results from it.

- 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.

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 XISMOM 60 XL IS AND WHAT IT IS USED FOR

The name of your medicine is XISMOM 60 XL. Prolonged Release Tablets (referred to as XISMOM 60 XL) throughout this leaflet.

XISMOM 60 XL contains the active ingredient isosorbide Mononitrate, which belongs to a group of medicines called nitrates. It is used to prevent an attack of angina pectoris (chest pain) from happening. 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. XISMOM 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE XISMOM 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.

Do not take XISMOM 60 XL if:
- you are allergic (hypersensitive) to isosorbide Mononitrate or any of the other ingredients of Xismox 60 XL (listed in Section 6. Further information)
- you have ever had a stroke
- you have very low blood pressure
- you have severe anaemia
- you have a heart problem called ‘cardiomyopathy’ or ‘pericarditis’ or you have narrow heart valves
- you are taking sildenafil or similar medicines called Phosphodiesterase Type 5 inhibitors (used for male impotence). See the section "Taking other medicines."
- 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**

Take special care with Xismox 60 XL

- 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 hypothyroidism (symptoms include shivering, abnormal drowsiness, confusion).
- If you suffer from malnutrition.
- If you suffer from severe liver or renal disease.
- Check with 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 any of the above apply to you, or you are not sure, talk to your doctor or pharmacist before taking Xismox 60 XL.

Children

This medicine is not suitable for children.

Other medicines and Xismox 60 XL

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained 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.

You should not take Viagra (sildenafil) or other medicines from this group such as Cialis (tadalafil) or Levitra (vardenafil), drugs used for erectile dysfunction (impotence in men), whilst on Xismox 60 XL.

If you take one of these drugs for erectile dysfunction, taking nitrate preparations such as XISMOM 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.

The following medicines may interfere with the way XISMOM 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 and breast-feeding**

XISMOM 60 XL should not be used during pregnancy or when breast-feeding an infant. Seek advice from your doctor if you become pregnant while taking this medicine.

**Driving and using machines**

Do not drive or operate machinery until you know how XISMOM 60 XL affects you and until you are confident that it won’t affect your driving. If you experience headache or dizziness following initial treatment with XISMOM 60 XL, speak to your doctor before you start driving or using machines.

XISMOM 60 XL contains lactose and sucrose if you have been told by your doctor that you have an intolerance to one or more sugars, contact your doctor before taking this medicinal product.
3. HOW TO TAKE XISMOX 60 XL
This medicine has been prescribed for you and you must take it exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. It is important that you take this medicine only once a day and at the same time each day. This is important to reduce the risk of your body becoming less sensitive to the effects of XISMOX 60 XL.
XISMOX 60 XL tablets should be swallowed with half a glass of water and must not be crushed or chewed.
The recommended dose is:
Adults: one XISMOX 60 XL tablet once daily in the morning.
Your doctor may advise a different dose according to your symptoms, age and other medications. Your dose may be from half a tablet (30 mg) up to 2 tablets (120 mg) a day, both to be taken in the morning.

Use in Children
This medicine is not recommended for children.

Use in 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 “Taking other medicines”).

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).

Very occasionally, some people 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.

If you take more XISMOX 60 XL than you should
If you take too many tablets, or someone else has taken any of them by accident, contact your nearest hospital casualty department or your pharmacist immediately.

Remember to take the following to show the doctor:
- the leaflet and container
- any remaining XISMOX 60 XL tablets
- any other medicines which you or the other person are taking.

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 to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, do not take the missed dose, just take the next dose on time. Do not take a double dose to make up for a forgotten dose.
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, XISMOX 60 XL can cause side effects, although not everybody gets them.

Serious side effects:
If you suffer from any of the following signs, tell your doctor immediately:
- Fainting may occur but is uncommon
- Rash and itching may occur but is rare.

Other side effects:
A number of side effects are known for isosorbide mononitrate, particularly when treatment begins.

Common (may affect up to 1 in 10 people)
- Headache is the most common side effect, but it usually disappears in time on continued use.
- Dizziness – this usually disappears with time
- Lowering of blood pressure (which may make you feel dizzy or sick) especially when getting up from a lying or sitting position, but this usually disappears in time on continued use
- Nausea (feeling sick)
- Tachycardia (fast heart beat).

Uncommon (may affect up to 1 in 100 people)
- Vomiting (being sick)
- Diarrhoea (loose bowel movements).

Very rare (may affect up to 1 in 10,000 people)
- Muscle pain.
- Severe liver or kidney disorder – in any case you should follow your doctor’s instructions. If you have any other unexpected effects whilst taking this medicine, tell your doctor or pharmacist immediately.

5. HOW TO STORE XISMOX 60 XL
Keep this medicine out of the sight and reach of children. These tablets should not be stored above 25°C. Do not transfer them to another container. Do not use XISMOX 60 XL after the expiry date which is stated on the blister and carton pack after ‘Exp’. The expiry date refers to the last day of that month. Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required or past their expiry date. 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 (60 mg).
- The other ingredients are colloidal anhydrous silica, hypromellose 2208, lactose monohydrate (milk sugar), compressible sugar (composed of sucrose and maltodextrin), magnesium stearate, iron oxide yellow E172.

What XISMOX 60 XL looks like and contents of the pack
XISMOX 60 XL tablets are light yellow, biconvex, oval-shaped, prolonged-release tablets, 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).

Marketing Authorisation Holder and Manufacturer:
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