

MONOSORB[®] XL 60 PROLONGED RELEASE TABLETS

(Isosorbide mononitrate)

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

Always take this medicine exactly as described in the 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 your doctor if you do not feel better or if you feel worse.

What is in this leaflet:

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

1. WHAT MONOSORB XL 60mg IS AND WHAT IT IS USED FOR

MONOSORB XL 60mg Prolonged release Tablets (referred to as MONOSORB XL 60mg throughout this leaflet) contains the active substance 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.
- It works by making the blood vessels relax and widen. This makes it easier for the heart to pump blood around the body, improving the supply of blood and oxygen to the heart muscle.

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 MONOSORB XL 60mg

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 MONOSORB XL 60mg:

- 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 the section "Other medicines and Monosorb XL 60mg".

Isosorbide mononitrate should not be used in

patients with acute myocardial infarction with low filling pressure, head trauma, cerebral haemorrhage and severe hypotension or hypovolaemia.

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

WARNINGS AND PRECAUTIONS

Talk to your doctor or pharmacist before taking Monosorb XL 60mg:

- 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 shivering, abnormal drowsiness, confusion).
- If you suffer from malnutrition.
- If you suffer from severe liver or renal disease.

Other medicines and Monosorb XL 60mg

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 Monosorb XL 60mg can affect the way some medicines work and some medicines can have an effect on Monosorb XL 60mg.

Do not take Monosorb XL 60mg 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 MONOSORB XL 60 mg as well can cause a severe and possibly 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 MONOSORB XL 60 mg works:

- noradrenaline (norepinephine) (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 MONOSORB XL 60 mg with alcohol

Avoid drinking alcohol while taking MONOSORB XL 60 mg, 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 experience headache or feel dizzy after taking Monosorb XL 60mg. If this happens, do not drive or use any tools or machines.



MONOSORB XL 60mg contains lactose and sucrose

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

3. HOW TO TAKE MONOSORB XL 60 mg

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 Monosorb XL 60mg a day.
- Take the medicine in the morning.
- Your doctor may ask you to start a low dose so you are less likely to have a reaction to starting Monosorb XL 60mg. Your dose may be from half a tablet (30mg) up to 2 tablets (120mg) a day.

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

Use in Children

Do not give these tablets to 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 MONOSORB XL 60 mg or existing treatment (see Section 2 "What you need to know before you take MONOSORB XL 60 mg").

If you take more MONOSORB XL 60mg than you should

If you take more Monosorb XL 60mg Tablets than you should, talk to a 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 MONOSORB XL 60mg

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

If you stop taking MONOSORB XL 60 mg Do not suddenly stop taking MONOSORB XL 60 mg 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.

Headache may occur when treatment is initiated but usually disappears after 1-2 weeks of treatment.

Hypotension with symptoms such as dizziness and nausea with syncope in isolated cases, has occasionally been reported. These symptoms generally disappear during continued treatment.

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 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 MONOSORB XL 60 mg

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- 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 MONOSORB XL 60 mg contains

- The active substance is isosorbide mononitrate. Each tablet contains 60 mg 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 MONOSORB XL 60mg looks like and contents of the pack

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

MONOSORB XL 60 mg tablets are available in packs of 28, 30 or 98 tablets in blister strips. Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer:

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

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