

## MONOSORB<sup>®</sup> XL 60 PROLONGED RELEASE TABLETS

(Isosorbide mononitrate)

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

This medicine is available without prescription. However, you still need to use MONOSORB XL 60mg 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 MONOSORB XL 60 mg is and what it is used for
2. What you need to know before you take MONOSORB XL 60 mg
3. How to take MONOSORB XL 60 mg
4. Possible side effects
5. How to store MONOSORB XL 60 mg
6. Contents of the pack and other information

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

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

**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 60 mg if:**

- you are allergic (hypersensitive) to isosorbide mononitrate or any of the other ingredients of Monosorb XL 60 mg (listed in Section 6: Contents of the Pack and Other 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 "What you need to know before you take Monosorb".

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

### WARNINGS AND PRECAUTIONS

**Take special care with MONOSORB XL 60 mg**

- 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 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 Monosorb XL 60 mg 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 Monosorb XL 60 mg.

### Children

This medicine is not suitable for children.

### Other medicines and Monosorb XL 60 mg

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 Monosorb XL 60 mg can affect the way some medicines work and some medicines can have an effect on Monosorb XL 60 mg. **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 MONOSORB XL 60mg.** 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 and breast-feeding

MONOSORB XL 60 mg should not be used during pregnancy or when breastfeeding 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 MONOSORB XL 60 mg affects you and until you are confident that it won't affect your driving. If you experience headache or dizziness following initial treatment with MONOSORB XL 60 mg, speak to your doctor before you start driving or using machines.

### MONOSORB XL 60 mg contains lactose and sucrose

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



### 3. HOW TO TAKE MONOSORB XL 60 mg

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 MONOSORB XL 60 mg.**

MONOSORB XL 60 mg tablets should be swallowed with half a glass of water and must not be crushed or chewed.

The recommended dose is:

Adults: one MONOSORB XL 60 mg 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 MONOSORB XL 60 mg or existing treatment (see Section 2 "What you need to know before you take Monosorb").

**You must not take Monosorb XL 60 mg 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 people see the remains 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 MONOSORB XL 60 mg 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 tell your doctor immediately.

Remember to take the following to show the doctor:

- the leaflet and container
- any remaining MONOSORB XL 60 mg 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 MONOSORB XL 60 mg

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 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, MONOSORB XL 60 mg 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 it 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

If you develop any of these side effects and they are severe, or they get worse, or last for more than a few days, contact your doctor or pharmacist. If you have any other unexpected effects whilst taking this medicine, tell your doctor or pharmacist immediately.



### 5. HOW TO STORE MONOSORB XL 60 mg

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 MONOSORB XL 60 mg 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 wastewater 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 MONOSORB XL 60 mg 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 Monosorb XL 60 mg looks like and contents of the pack

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

MONOSORB XL 60 mg tablets is 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.

This leaflet was last revised in March 2014.

