

ISOMEL SR 60mg
PROLONGED-RELEASE TABLETS
(Isosorbide mononitrate)

Please read all of this leaflet carefully before you start taking Isomel SR 60mg Prolonged Release Tablets 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT ISOMEL SR 60 mg IS AND WHAT IT IS USED FOR

The name of your medicine is ISOMEL SR 60 mg Prolonged-Release Tablets (referred to as ISOMEL SR 60 mg throughout this leaflet). ISOMEL SR 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. ISOMEL SR 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 ISOMEL SR 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 ISOMEL SR 60 mg if:

- you are allergic (hypersensitive) to isosorbide mononitrate or any of the other ingredients of Isomel SR 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 ISOMEL”.

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

WARNINGS AND PRECAUTIONS

Take special care with ISOMEL SR 60 mg

- If you have labile (unsteady) circulation. Speak with your doctor as treatment may be started with a 30 mg 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 Isomel SR 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 Isomel SR 60 mg.

Children

This medicine is not suitable for children.

Other medicines and Isomel SR 60mg

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 Isomel SR 60 mg can affect the way some medicines work and some medicines can have an effect on Isomel SR 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 ISOMEL SR 60mg.** If you take one of these drugs for erectile dysfunction, taking nitrate preparations such as ISOMEL SR 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 ISOMEL SR 60 mg 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 ISOMEL SR 60 mg with alcohol

Avoid drinking alcohol while taking ISOMEL SR 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

ISOMEL SR 60 mg 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 ISOMEL SR 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 ISOMEL SR 60 mg, speak to your doctor before you start driving or using machines.

Isomel SR 60 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 ISOMEL SR 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 ISOMEL SR 60 mg.

ISOMEL SR 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 ISOMEL SR 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 ISOMEL SR 60 mg or existing treatment (see Section 2 "What you need to know before you take ISOMEL").

You must not take Isomel SR 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 ISOMEL SR 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 ISOMEL SR 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 ISOMEL SR 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 ISOMEL SR 60 mg

Do not suddenly stop taking ISOMEL SR 60 mg, 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, ISOMEL SR 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.

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

HPRA Pharmacovigilance,
Earlsfort Terrace, IRL – Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ISOMEL SR 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 ISOMEL SR 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 ISOMEL SR 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 Isomel SR 60 mg looks like and contents of the pack

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

ISOMEL SR 60 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.

Distributor:

Clonmel Healthcare Ltd.
Waterford Road, Clonmel, Co. Tipperary, Ireland

This leaflet was last revised in July 2014.

CLONMEL HEALTHCARE LTD
CLONMEL, IRELAND

