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PACKAGE LEAFLET: INFORMATION FOR THE USER

Monomil XL Tablets

(isosorbide-5-mononitrate)

Read all of this leaflet carefully before you start taking this medicine 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Monomil XL Tablets are and what are they used for
2. What you need to know before you take Monomil XL Tablets
3. How to take Monomil XL Tablets
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1. What Monomil XL Tablets are and what are they used for

Monomil XL contains a medicine called isosorbide mononitrate. This belongs to a group of medicines called 'nitrates'.

- It is used to prevent chest pain (angina).
- It works by making the blood vessels relax and widen. This makes it easier for the heart to pump blood around the body.

2. What you need to know before you take Monomil XL Tablets

Do not take Monomil XL Tablets:

- If you are allergic (hypersensitive) to isosorbide mononitrate or any of the other ingredients in the tablets (see Section 6 and end of Section 2).
- If you suffer from a condition called constrictive pericarditis (inflammation of the lining around the heart), or cardiac tamponade (where the fluid around the heart puts pressure on the heart).
- If you are having a heart attack (acute myocardial infarction)
- If you suffer from very low blood pressure (hypotension)
- If you suffer from a condition called aortic stenosis (narrowing of the main artery coming from the heart).
- If you suffer from a condition called mitral stenosis (narrowing of the mitral valve on the left side the heart).
- If you suffer from a condition called hypertrophic cardiomyopathy (a heart disease which causes the heart muscle to become thick and can cause symptoms such as chest pain, dizziness and collapse).
- If you suffer from a condition which can increase the pressure on the brain e.g. a recent serious head injury and bleeding into the brain (cerebral haemorrhage).
- If you suffer from severe anaemia (reduction in the number of red blood cells)
- If you suffer from closed angle glaucoma (a condition which can causes sudden attack of eye pain due to rapid increases in eye pressure, with symptoms such as blurred

vision, painful red eye and headache)

- If you are taking any medicines for erectile problems, such as Viagra (Sildenafil), which belong to a group of medicines called phosphodiesterase type 5 inhibitors (see section 'Other Medicines and Monomil XL Tablets').
- are in the first three months of pregnancy

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Monomil XL Tablets if you.

- you ever had any serious damage to your heart, such as a heart attack or operation.
- suffer from liver or kidney disease
- suffer from hypothyroidism (underactive thyroid gland)
- suffer from hypothermia (very low body temperature)
- suffer from malnutrition (severe lack of food)
- drink alcohol - alcohol should be avoided during treatment with Monomil XL Tablets.

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

Reminder

This medicine should not be used to treat a sudden angina attack. Your doctor should prescribe (GTN) glyceryl trinitrate (tablets or spray) if you have a sudden angina attack. Monomil XL Tablets is used to **prevent** attacks of angina, and should be used regularly, as prescribed by the doctor.

Other Medicines and Monomil XL Tablets

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 Monomil XL tablets can affect the way some medicines work and some medicines can have an effect on Monomil XL tablets.

Do not take Monomil XL tablets if you are taking the following medicines:

- medicines which reduce blood pressure such as:
 - ACE inhibitors, e.g. enalapril, captopril
 - beta-blockers, e.g. atenolol, propranolol
 - calcium channel blockers, e.g. diltiazem, verapamil, nifedipine
 - angiotensin II receptor antagonists, e.g. candesartan
 - Sildenafil or similar medicines called phosphodiesterase Type 5 inhibitors, (used for male impotence).
 - alprostadil used to treat erectile dysfunction
 - aldesleukin used to treat kidney cancer and melanoma
- benzodiazepines, e.g. temazepam
- tricyclic antidepressants, e.g. amitriptyline.

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

Pregnancy and breast-feeding

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 dizziness when you start taking Monomil XL Tablets. If this happens, do not drive or use any tools or machines

Important information about some of the ingredients of Monomil XL Tablets

These tablets contains lactose. Consult your doctor if you have been told you have an

intolerance to some sugars before taking these tablets.

3. How to take Monomil XL Tablets

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

Taking this medicine

- Swallow the tablets whole or broken in half (if this is easier to swallow).
- Take the tablets with half a glass of water.
- Do not crush or chew the tablets.

How much to take

Adults: The recommended dose is one tablet taken once daily in the morning. This may be increased to two tablets on the advice of your doctor, in which case both tablets should be taken once daily in the morning.

Treatment is sometimes started for the first 2-4 days, with 30mg tablet once daily in the morning in order to minimise the possibility of headache.

The score line on the tablet is not intended to divide the tablet into equal halves.

Elderly: The usual dose is the same as the adult dose.

Children: Not recommended for use in children.

You must not take Monomil XL 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 Monomil XL Tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child has swallowed any of these tablets, contact your nearest hospital casualty department or your doctor immediately. Take this leaflet and your tablets with you. The symptoms of an overdose may be pulsing headache, reddening of the skin, cold perspiration, nausea, vomiting and a fast heart beat.

If you forget to take Monomil XL Tablets

If you forget to take your tablet(s) but remember within 12 hours of your usual time, take it when you remember. If you remember more than 12 hours after your usual time, don't take the tablet and just carry on with the next dose when it is due.

If you stop taking Monomil XL Tablets

Do not stop taking your tablets without first discussing this with your doctor as this may be harmful.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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:

- Headache
 - Feeling sick (nausea)
 - Feeling dizzy
- The above problem 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 or dizzy)
- Faster heartbeat (tachycardia)

- 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 of 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: 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 Monomil XL Tablets

Keep this medicine out of the sight and reach of children.

Store your tablets in the original package.

Do not store above 25°C

Do not use your medicine after the expiry date shown on the carton.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Monomil XL Tablets contain

Each tablet contains 60mg of the active ingredient isosorbide-5-mononitrate.

The other substances are lactose monohydrate, hypromellose, maize starch, glyceryl palmitostearate and magnesium stearate.

What Monomil XL Tablets looks like and contents of the pack

The tablets are white, capsule shaped, biconvex and uncoated with scoring. They are supplied in carton containing two strip of blister packs - each strip containing 14 tablets (28 tablets per carton)

Marketing Authorization Holder and Manufacturer

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