

Chemydur[®] 60XL Tablets

Isosorbide-5-mononitrate



AMDIPHARM

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

- Please 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 symptoms 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.

What is in this leaflet:

1. What Chemydur 60XL Tablets are and what they are used for.
2. What you need to know before you take Chemydur 60XL Tablets.
3. How to take Chemydur 60XL Tablets.
4. Possible side effects.
5. How to store Chemydur 60XL Tablets.
6. Contents of the pack and other information.

1. WHAT CHEMYDUR 60XL TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Chemydur 60XL Tablets. The active ingredient is isosorbide-5-mononitrate. Chemydur 60XL Tablets belong to a group of medicines called nitrates. Chemydur 60XL Tablets are used in adults to prevent angina (chest pain) and work by opening up blood vessels and reducing the pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CHEMYDUR 60XL TABLETS

Do not take Chemydur 60XL Tablets if you:

- are allergic to isosorbide-5-mononitrate or any of the other ingredients of Chemydur 60XL Tablets listed in section 6 (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing);
- have any inflammation of the heart such as pericarditis;
- have been diagnosed with any of the following heart conditions
 - Low cardiac filling pressure
 - Cardiac tamponade
 - Hypertrophic obstructive cardiomyopathy;
- have had any serious damage to your heart, such as a cardiomyopathy or have narrow heart valves;
- suffer from severe anaemia (low levels of red blood cells in the blood);
- have a low volume of blood in your body (hypovolaemia);
- have a head injury or bleeding of the brain;
- have closed-angle glaucoma (high pressure in the eyes);
- have low blood pressure (hypotension);
- have decreased blood supply to the brain (cerebrovascular insufficiency);
- are taking a medicine called Viagra (sildenafil) used for male erectile dysfunction.

Warnings and precautions

Talk to your doctor or pharmacist before taking Chemydur 60XL Tablets if you:

- have recently had a heart attack;
- have an underactive thyroid gland (hypothyroidism);
- have angina due to other causes (such as a large heart muscle), or have an increased circulatory volume;
- have a head injury or bleeding of the brain;
- develop low blood pressure (hypotension), a slow heart rate (bradycardia), or worsening of your angina;
- are at risk of having a stroke;
- have liver or kidney problems, especially if you are elderly;
- have cirrhosis of the liver;
- have a poor diet;
- have poor circulation;
- have consumed alcohol as this may lead to low blood pressure (hypotension);
- feel that you are developing a tolerance to Chemydur 60XL Tablets;
- have a very low body temperature (hypothermia).

If you have an attack of angina whilst taking Chemydur, do not stop taking your Chemydur 60XL Tablets. Your doctor will provide another medicine to treat your condition.

Children

Chemydur 60XL Tablets are not suitable for use in children.

Other medicines and Chemydur 60XL Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken, or might take any other medicines, including medicines obtained without a prescription.

It is especially important to tell your doctor if you are taking;

- medicines used to treat high blood pressure (e.g. propranolol, furosemide);
- medicines used to treat heart failure (e.g. nifedipine, ramipril);
- medicines used in the treatment of erectile dysfunction (e.g. sildenafil);
- any medication which may cause a lowering of your blood pressure (e.g. causing dizziness or light-headedness, especially on standing);
- medicines such as noradrenaline, which are used to treat high blood pressure or a heart attack;
- acetylcholine, which is used during some operations;
- medicines such histamine, which is used to treat allergic reactions;
- medicines used to treat migraines (e.g. ergotamine).

Chemydur 60XL Tablets with food, drink and alcohol

You should avoid alcohol while taking Chemydur 60XL as it may increase the feeling of dizziness you may experience.

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. The safety of Chemydur 60XL Tablets during pregnancy or whilst breast-feeding has not been established.

Driving and using machines

You can drive while taking Chemydur 60XL Tablets but do not drive until you know how the tablets affect you. They may give you low blood pressure or make you feel dizzy, if they affect you in this way, **do not** drive or operate any machinery.

Chemydur 60XL Tablets contain lactose

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

3. HOW TO TAKE CHEMYDUR 60XL TABLETS

Always take Chemydur 60XL Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose for adults is **1 or 2 tablets** a day, taken in the morning.

A dose of half a tablet may be prescribed for the first 2-4 days.

The tablets should be **swallowed** with half a glass of water. Do not crush or chew the tablets.

If Chemydur 60XL Tablets are taken frequently and for long periods the effectiveness of the drug may decrease. If you notice that your tablets are no longer working as well at relieving the pain as they have done before, consult your doctor.

If you take more Chemydur 60XL Tablets than you should

If you take more Chemydur 60XL than you should, contact your doctor or nearest hospital emergency department immediately.

Take this leaflet and any remaining tablets with you. Symptoms of overdose include headache, feeling over-excited, flushing, cold perspiration, feeling sick, being sick, feeling dizzy, fainting, a fast heart beat, low blood pressure, confusion, shortness of breath and unconsciousness.

If you forget to take Chemydur 60XL Tablets

If you forget to take a dose, just take the next dose at the usual time, **DO NOT** take a double dose.

If you stop taking Chemydur 60XL Tablets

Ask your doctor before stopping treatment with Chemydur 60XL, as treatment should be reduced gradually over several days and you must be monitored carefully by your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Chemydur 60XL Tablets can cause side effects, although not everyone gets them.

Headaches may occur when treatment is first started, but this usually disappears after 1 to 2 weeks of treatment.

Other side effects include:

- feeling dizzy;
- low blood pressure when standing up (postural hypotension), which may make you feel sick or dizzy;
- slow heart beat;
- fast heart beat;
- flushing;
- restlessness;
- looking pale;
- weakness;
- tiredness;

- cold perspiration.

Rarely, these side effects can occur:

- rash and itching;
- pain in your muscles or joints;
- drowsiness;
- feeling sick, being sick and diarrhoea;
- sensitivity to light;
- fainting or collapse;
- low levels of oxygen in the blood;
- bleeding in the brain;
- your angina may worsen.

Very rarely, these side effects can occur:

- red or scaly skin (exfoliative dermatitis).

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, website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

If Chemydur 60XL Tablets are taken frequently and for long periods the effectiveness of the drug may decrease. If you notice that your tablets are no longer working as well at relieving the pain as they have done before, consult your doctor.

5. HOW TO STORE CHEMYDUR 60XL TABLETS

Do not use after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Store your medicine in a dry place below 25°C. Keep it out of direct sunlight.

KEEP THIS MEDICINE OUT OF SIGHT AND REACH OF CHILDREN.

6. CONTENT OF THE PACK AND OTHER INFORMATION What Chemydur 60XL Tablets contain

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

The other ingredients are: Polyethylene glycol 4000, hydroxypropyl methylcellulose, stearic acid, talc, purified siliceous earth, lactose, carnauba wax, magnesium stearate and the colourings titanium dioxide (E171) and yellow iron oxide (E172).

What Chemydur 60XL Tablets look like and contents of the pack

Chemydur 60XL Tablets are oval, cream-coloured tablets with a score line on both sides and a crown and '60' on one side. They are packaged in blister packs of 28, 30, 56, 60 and 100 tablets.

Not all packs sizes may be marketed.

Marketing Authorisation Holder:

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