

Monomax[®] XL 60 mg Tablets

Isosorbide 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.

What is in this leaflet:

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1. What Monomax is and what it is used for

Monomax XL Prolonged-release Tablets contain isosorbide mononitrate which belongs to a group of medicines called nitrates that act on the cardiovascular system (the heart and blood vessels). Monomax has been given to you by your doctor or pharmacist to reduce the frequency of your anginal attacks (chest pains). They are called prolonged-release tablets because they are manufactured in a way that allows the isosorbide mononitrate to be released and slowly absorbed by your body over a period of several hours.

In angina, isosorbide mononitrate works by opening up the arteries supplying the heart muscle and this allows more blood and oxygen to reach the muscle, decreasing the chances of angina (chest pains) occurring when extra strain is placed upon the heart.

2. What you need to know before you take Monomax

Do not take Monomax:

- **if you are taking the drug, sildenafil or similar medicines called Phosphodiesterase Type 5 Inhibitors, for the treatment of male erectile dysfunction** (see also: Section 2 - Taking other medicines)
- if you are allergic to isosorbide mononitrate, other nitrates (e.g glyceryl trinitrate or isosorbide dinitrate) or any of the other ingredients in Monomax (listed in section 6)
- if you have suffered a stroke or have any other condition which may affect the blood supply to your brain
- if you suffer from low blood pressure
- if you have been told that you have a problem with your heart such as 'cardiomyopathy' or 'pericarditis' or you have narrow heart valves. Ask your doctor if you are not sure if this applies to you
- if you suffer from a reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- to treat an angina attack as it occurs. Your doctor will probably have given you another tablet to take for sudden attacks.

Take special care with Monomax and always tell your doctor or pharmacist if:

- you suffer from increased pressure in your eyes
- you suffer from an underactive thyroid gland
- you suffer from an abnormally low body temperature
- you suffer from poor health caused by a poor diet
- you suffer from severe liver or kidney disease
- you have suffered from a head injury or bleeding in the brain
- you have ever had any serious damage to your heart, such as a heart attack or operation.

Taking other medicines

Before starting treatment, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you have to go to a doctor, dentist or hospital for any reason, tell them that you are taking Monomax.

In particular, tell your doctor or pharmacist if you are taking:

- medicines for the treatment of high blood pressure, such as hydralazine or minoxidil
- water tablets, such as frusemide

Taking these types of medicines with Monomax can increase the risk of low blood pressure occurring, especially if you are elderly.

Do not take sildenafil, or similar medicines called Phosphodiesterase Type 5 Inhibitors used for the treatment of erectile dysfunction at the same time as Monomax. If taken at the same time it could cause a severe fall in blood pressure resulting in collapse, unconsciousness and may be fatal.

Taking Monomax with food, drink and alcohol:

If you drink alcohol while you are taking Monomax it can increase the risk of low blood pressure occurring, especially if you are elderly.

Pregnancy, breast-feeding and fertility:

Do **not** take Monomax if you are pregnant, trying to become pregnant or are breast-feeding.

Driving and using machines:

If you feel faint, dizzy or light headed when you stand up or move suddenly after taking Monomax, then **do not drive or operate machinery**.

Important information about some of the ingredients of Monomax:

Monomax contains lactose monohydrate. 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 Monomax

Always take Monomax exactly as your doctor or pharmacist has told you to. You should check with your doctor or pharmacist if you are not sure.

The label on the carton will tell you how many tablets you should take and when. It is very important that you take your tablets regularly. **Do not stop** treatment even if you feel better unless told to do so by your doctor.

Monomax is formulated so that you only have to take your tablets **once a day**.

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It is important that you take your tablets **at the same time each day**, preferably in the morning. Your tablet may be swallowed whole or broken in half if this is easier and swallowed with a glass of water. **Do not crush or chew your tablets.**

Adults and the elderly: the usual dose is 60 mg **once** a day. Your doctor may decide to increase your dose to a maximum of 120 mg of Monomax once a day. To reduce the possibility of headaches you may initially be given half a tablet (30 mg) once a day for the first 2-4 days.

If you are elderly and suffer from low blood pressure, liver or kidney disease, your doctor may prescribe a lower dose for you to take.

Do **not** stop taking your medicine until your doctor tells you.

Children must **not** take this medicine.

You must not take Monomax 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 Monomax than you should

If you accidentally take more Monomax than you should, contact your nearest casualty department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining tablets with you.

If you forget to take Monomax

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

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

4. Possible side effects

Like all medicines, Monomax can cause side effects, although not everyone gets them.

If you experience a **headache** when you first start taking your tablets, contact your doctor or pharmacist immediately. Your doctor or pharmacist may need to adjust your dose.

The following side effects do not usually last long and are most likely to occur when you first start to take your medicine or if your dose has been increased. If they continue or if you are worried, contact your doctor or pharmacist immediately:

- light headedness when you stand up or move suddenly
- faintness
- feeling sick (nausea)
- flushing

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

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 the YellowCard Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Monomax

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original packaging.
- Do not use Monomax after the expiry date which is stated on the blister and carton. 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. These measures will help protect the environment.

6. Contents of the pack and other information

What Monomax contains:

- The active substance in your tablets is isosorbide mononitrate. Each tablet contains 60 mg of isosorbide mononitrate.
- The other ingredients are lactose monohydrate, hypromellose (E464), glyceryl palmitostearate, maize starch and magnesium stearate.

What Monomax looks like and the contents of the pack:

Monomax XL 60 mg Prolonged Release Tablets are white, oval and convex in shape with a break line between "SL" and "60", which are embossed on one side. They are available in blister packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer:

The Marketing Authorisation holder and manufacturer is Chiesi Limited, 333 Styal Road, Manchester, M22 5LG, UK.

Is this leaflet hard to see or read? Phone 0161 488 5555 for help.

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