

PACKAGE INFORMATION LEAFLET: INFORMATION FOR THE PATIENT
EUMON 40 XL Modified Release 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.
- 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 this medicine is and what it is used for
2. What you need to know before you take Eumon 40 XL
3. How to take Eumon 40 XL
4. Possible side effects
5. How to store Eumon 40 XL
6. Contents of the pack and other information

1 What this medicine is and what it is used for

Eumon 40 XL belongs to a group of medicines called anti-anginals (organic nitrates) and is used to prevent chest pain (angina pectoris).

It works by opening up blood vessels and reducing the pain.

2 What you need to know before you take

Do not take Eumon 40 XL if:

- You are allergic (hypersensitive) to isosorbide mononitrate, other nitrates or any of the other ingredients of this medicine (see section 6 "Contents of the pack and other information")
- You have very low blood pressure
- You are at risk of having a stroke, if you are at risk of increased pressure in your skull (increased intracranial pressure) if you have had a bleed in the brain or suffered a recent blow to the head or head injury
- You have had an acute (short-lived) heart attack (myocardial infarction)
- You are suffering from shock or vascular collapse which causes the blood to stop circulating around your body (acute circulatory failure)
- You have a heart condition which causes the heart muscle to become thick (hypertrophic obstructive cardiomyopathy). This can cause chest pain, dizziness, fainting, heart failure, light-headedness, feeling the heartbeat (palpitations) and shortness of breath
- You have inflammation of the lining surrounding the heart which can cause difficulty breathing, tiredness, swelling of the ankles and feet and feeling weak (constrictive pericarditis)
- You have narrowing of the main artery, which may cause breathlessness, dizziness, fainting or chest pain (aortic stenosis)
- You have narrowing of the mitral valve, which may cause shortness of breath, fainting, dizziness, tiredness, irregular heartbeat and chest pain (mitral stenosis)
- You have a severe reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (severe anaemia)
- You suffer from excessive fluid around the heart which can cause anxiety, restlessness, difficult or rapid breathing, swelling of the abdomen, fainting or light-headedness, feeling the heartbeat and chest pain (cardiac tamponade)

- You have a low water content of the blood, which may cause an increase in pulse rate, low blood pressure, pale skin, feeling dizzy or faint and feeling very thirsty (hypovolaemia)
- You have a rapid increase in pressure in the eye, which can cause pain, red eye, blurred vision and headache (closed-angle glaucoma)
- You are taking viagra (sildenafil) for erectile dysfunction or other phosphodiesterase-5-inhibitors e.g. tadalafil or vardenafil. (See “Other medicines and Eumon 40 XL” section)
- You are taking riociguat e.g. Adempas for pulmonary hypertension. (See “Other medicines and Eumon 40 XL” section)

Warnings and precautions

Talk to your doctor before taking Eumon 40 XL:

- If you suffer from an underactive thyroid gland (hypothyroidism)
- If you have a poor diet and your body lacks nutrients (malnutrition)
- If you have severe kidney or liver problems
- If you suffer from a very low body temperature (hypothermia)
- If you have recently had a heart attack (myocardial infarction)
- If you suffer from postural hypotension - a fall in blood pressure on standing making you dizzy and feeling faint

This medicine should not be used to treat an angina attack. Your doctor should prescribe buccal glyceryl trinitrate or sublingual tablets for you to take if you have an angina attack

Other medicines and Eumon 40 XL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Do not take Eumon 40 XL if you are taking riociguat, e.g. Adempas for pulmonary hypertension. When taken together, a fall in blood pressure can occur.

Medicines which **may interact with or be affected by** Eumon 40 XL:

- Viagra (sildenafil) for erectile dysfunction or other phosphodiesterase-5-inhibitors e.g. tadalafil or vardenafil. (see 'Do not take' section)
- Hydralazine for high blood pressure (antihypertensive)
- Vasodilators, such as diazoxide
- Calcium channel blockers, such as diltiazem
- Diuretics (water tablets)
- ACE inhibitors, such as captopril
- Beta-blockers, such as atenolol
- Angiotensin II receptor antagonists, such as losartan
- Alprostadil for erectile dysfunction
- Aldesleukin for kidney cancer and melanoma
- Dihydroergotamine for migraines

Taking Eumon 40 XL with alcohol

If you drink alcohol whilst taking Eumon 40 XL it may cause a severe drop in blood pressure making you feel dizzy or light-headed, especially on standing up (postural hypotension).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

This medicine should only be used during pregnancy if your doctor thinks the benefits outweigh the possible risks.

Breast-feeding

This medicine should only be used whilst breast-feeding if your doctor thinks the benefits outweigh the possible risks.

Driving and using machines

This medicine may make you feel dizzy, light-headed or cause blurred vision. If affected, do not drive or operate machinery.

Eumon 40 XL contains 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 Eumon 40 XL

Always take Eumon 40 XL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- These tablets should be swallowed whole with half a glass of water
- These tablets should **not** be crushed or chewed

Adults

- The usual dose for adults is 1 tablet (40mg) taken in the morning. Your doctor may increase this dose to 2 tablets (80mg), to be taken at the same time.
- In order to minimise the possibility of headache, your doctor may tell you to take a smaller dose for the first 2 – 4 days.

Older people

- The usual dose for older people is as for adults.
- However, your doctor will take special care, if you have low blood pressure (hypotension) or liver or kidney disease.
- The lowest effective dose should be used.

Use in children

This medicine is **not** recommended for children.

If you take more Eumon 40 XL than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of an overdose may include: headache, excitation, cold sweat, feeling or being sick, feeling of dizziness or 'spinning', restlessness, warm flushed skin, blurred vision, fainting, faster heartbeat, fall in blood pressure, feeling your heartbeat (palpitations), confusion and neurological problems, such as difficulty speaking and loss of balance.

Other symptoms are a bluish appearance of the skin, change in mental state, difficulty breathing, fits, irregular heartbeat and circulation failure.

If you forget to take Eumon 40 XL

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

If you stop taking Eumon 40 XL

- It is important to keep taking Eumon 40 XL for as long as your doctor has told you to.
- Treatment with Eumon 40 XL should not be stopped suddenly. When stopping, your doctor will help you to reduce the dose and frequency gradually. This should be done over several days and you should be monitored by your doctor.

4 Possible side effects

Like all medicines, Eumon 40 XL can cause side effects, although not everyone gets them.

Seek medical advice immediately if you develop the following:

- Allergic reactions: swelling of the face, throat or tongue, fever, difficulty in breathing, dizziness

Very common side effect (may affect more than 1 in 10 people)

- Headache. A throbbing headache may occur when treatment is started. This usually disappears after 1 or 2 weeks of treatment

Other side effects (frequency not known)

- Low blood pressure (hypotension) including postural hypotension (a drop in blood pressure on standing from a lying or sitting position), which may cause dizziness, tiredness and nausea (feeling sick). Flushing and allergic reactions (including rashes) can also occur. These symptoms usually disappear during long-term treatment
- Severely low blood pressure, which may cause vomiting (being sick), restlessness, pale skin colour and excessive sweating. Although uncommon, collapse (sometimes with a slow heartbeat and fainting) and increased symptoms of chest pain (angina) may occur
- Dizziness
- Feeling (nausea) or being sick (vomiting)
- Increased (tachycardia) or decreased (bradycardia) heart rate
- Muscle pain (myalgia)
- Drowsiness
- Diarrhoea
- Scaling of the 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 at 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 Eumon 40 XL

- Keep this medicine out of the sight and reach of children
- Do not use this medicine after the expiry date which is stated on the carton/blister after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Eumon 40 XL contains:

Each modified release tablet contains 40mg of isosorbide mononitrate.

The other ingredients are: hypromellose, stearic acid, talc, silica colloidal anhydrous, lactose, carnauba wax, magnesium stearate, macrogol 4000, titanium dioxide (E171) and iron oxide (E172).

What Eumon 40 XL look like and the contents of the pack:

Eumon 40 XL are round, biconvex, cream coloured, modified release tablets with an approximate diameter of 8mm x 4.5mm, marked "IM40" on one side.

Eumon 40 XL is available in:

Eumon 40 XL modified release tablets are available in packs of 28, 30, 56, 60 or 100 tablets.

Not all pack sizes may be marketed.

Product Licence Number:

PL 11311/0455

Marketing Authorisation Holder and Manufacturer:

Tillomed Laboratories Limited
220 Butterfield,
Great Marlings,
Luton,
LU2 8DL.
United Kingdom

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