Lustra

PATIENT INFORMATION LEAFLET
Lustra 5 mg & 10 mg Tablets

Keep this leaflet. You may need to read it again.
Ask your doctor or pharmacist if you need more information or advice.
This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

Name of the medicine:
LUSTRA 5 mg 30 tablets
LUSTRA 10 mg 30 tablets

Composition:
Each tablet contains either 5mg or 10mg of the active ingredient Amlodipine (as amlodipine besilate monohydrate).
The tablets also contain microcrystalline cellulose, calcium hydrogen phosphate dihydrate, sodium starch glycollate and magnesium stearate.

MA holder/ Manufacturer:
Bluepharma Indústria Farmacêutica S.A.
S. Martinho do Bispo
3045-016 Coimbra
Portugal

1. WHAT LUSTRA TABLETS ARE AND WHAT ARE THEY USED FOR

Amlodipine is one of a group of medicines called calcium antagonists. These medicines work by relaxing blood vessels, so that blood passes through them more easily. In patients with a certain type of chest pain called angina, amlodipine works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. Lustra (Amlodipine) Tablets do not provide immediate relief of chest pain from angina.

MEDICINAL PRODUCT SUBJECT TO MEDICAL PRESCRIPTION.

2. BEFORE TOU TAKE LUSTRA TABLETS:

Do not take Lustra Tablets if you:
Have ever had an allergic reaction to Amlodipine Tablets or any of the ingredients in the tablet. (Please refer to composition)

Check with your doctor or pharmacist before taking Lustra Tablets if you:
Have ever had any disease. Treatment with Amlodipine tablets demands a medical periodic control.
Amlodipine tablets must be taken with precaution and within medical vigilance in patients with liver disease. In these cases, doctor may prescribe a different dose to normal.

Pregnancy and Breast-feeding:
If you are pregnant or likely to become pregnant, ask your doctor or pharmacist for advice before taking any medicine.
There are no adequate data from the use of Amlodipine Tablets in pregnant women. If you are pregnant or think you may be, you should only take Amlodipine Tablets once your doctor has confirmed that the benefits of treatment outweigh the risks to the baby. Amlodipine Tablets should not be used during pregnancy unless clearly necessary.

Driving and using machines:
Lustra (Amlodipine) Tablets is unlikely to affect your ability to drive or use machines.

Children:
Lustra Tablets is not recommended for use in children due to insufficient data. The experience in children is limited.

Elderly:
Your doctor will closely monitor your response to any dose increase.

Other precautions you should take:
If you see another doctor or go into hospital, let them know what medicines you are taking.

Patients with liver disease:
You can take Amlodipine tablets. Amlodipine is not eliminated by dialysis.

Taking Lustra tablets with other medicines :
There is no knowledge about relevant interactions between amlodipine and other medicines or food.
Amlodipine has been safely used with diuretics, other anti-hypertensive drugs, non-steroid anti-inflammatory drugs, antibiotics and oral blood glucose lowering drugs.
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. HOW TO TAKE LUSTRA TABLETS

Follow your doctor's instructions. If you are still unsure ask your pharmacist or doctor.
Oral use. The whole tablet must be taken with water or another non alcoholic drink, with or without food and preferably always at the same hour.

The usual dosage(s) are described below:

Adult
The usual dose is a 5mg tablet once daily. Your doctor may increase the dose to one 10mg tablet once daily after 2-4 weeks if necessary. According to the patient response, this dose can be increased until a 10 mg maximum dose. Amlodipine tablets can be taken with other medicines used for the treatment of hypertension and angina (diuretics, beta-blockers and ACE Inhibitors) without changing Amlodipine dosage.

Amlodipine is used in prolonged treatments. These treatments should not be interrupted even if you are feeling better, unless your doctor tells you.

If you take more Lustra Tablets than you should
If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Take any remaining tablets and the packaging with you to the doctor or casualty department. If an overdose has been taken there may be signs of intensely decrease of the arterial pressure such as flushing (reddening of the skin), feeling dizzy or fainting.

If you forget to take Lustra Tablets
If you forget to take a tablet take one as soon as you remember, unless it is nearly time to take the next one. Never take two doses together. Take the remaining doses at the correct time.

4. AFTER TAKING YOUR MEDICINE

Like all medicines, Amlodipine Tablets can sometimes cause unwanted side effects. The most common symptoms are: Headache, tiredness, dizziness, weakness, palpitations, feeling sick, heartburn, stomach ache, flushing of the face and feeling hot.

With less frequency the following symptoms may happen:

Uncommon (occur in between 1 in 1000 and 1 in 100 people)
Enlarged breasts in men (gynaecomastia), a general feeling of being unwell, dry mouth, involuntary shakiness, numbness, tingling or pins and needles, increased sweating, sight problems, problems sleeping, irritability, depression, fainting, fast heartbeat, chest pain, worsening of angina (at start of treatment), isolated cases of heart attack, irregular heartbeat or chest pain (in those patients who already have coronary artery disease), low blood pressure, difficulty breathing, runny nose, being sick, diarrhoea, constipation, swollen gums, rashes which may be itchy, itching, hair loss, skin discolouration, muscle cramps, back, muscle or bone pain, urinating more often, reduced sexual performance, weight loss or gain, ringing in the ears.

Rare (occur in between 1 in 10000 and 1 in 1000 people)
Confusion, mood changes (including anxiety), raised liver enzymes (detected in a blood test), yellowing of the skin or whites of the eyes (jaundice, hepatitis).

Very Rare (occur in less than 1 in 10000 people)
Changes in numbers and types of blood cells detected through a blood test (leukocytopenia, thrombocytopenia), raised blood sugar levels, problems feeling through fingers and toes due to nerve problems (peripheral neuropathy), inflammation of blood vessels, the stomach or pancreas, cough.
Tell your doctor if you notice or are worried by any of the side effects listed. Tell your doctor or pharmacist if you notice any other effects not listed.

STORING YOUR MEDICINE

Do not use the tablets after the end of the expiry month (use by date) shown on the product packaging.
Do not store the tablets above 25°C.
Store in the original package.
Keep Lustra Tablets out of the reach and sight of children in a secure place.
Return all unused medicines to your pharmacist for safe disposal.
Ask your doctor or pharmacist if you need more information or advice.