

LOTENSE CAPSULE

Amlodipine Besylate (5mg, 10mg)

1. WHAT IS IN THIS LEAFLET?

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2. WHAT LOTENSE IS USED FOR

Lotense is one of a group of medicines called calcium antagonists.

Lotense is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina.

3. HOW LOTENSE WORKS

In patients with high blood pressure Lotense works by relaxing blood vessels, so that blood passes through them more easily. The mechanism by which amlodipine relieves angina is not fully determined.

4. BEFORE YOU TAKE LOTENSE

When you must not take it

Do not use Lotense if you are allergic to amlodipine (the active ingredient in Lotense), or to the inactive ingredients. Your doctor or pharmacist can give you a list of these ingredients.

Before you start to take it

Tell your doctor if you:

- ever had heart disease
- ever had liver problems
- are pregnant, or plan to become pregnant. Your doctor will decide if Lotense is the best treatment for you.
- are breast-feeding. Do not breast-feed while taking Lotense. You can stop breastfeeding or take a different medicine.

Taking other medicines

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

5. HOW TO TAKE LOTENSE

How much to use

For both hypertension and angina the usual initial dose is 5mg amlodipine once daily which may be increased to a maximum dose of 10mg depending on the individual patient's response.

When to use it

It is best to take your medicine at the same time each day with a drink of water.

How long to use it

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

It is important to keep taking the capsules. Do not wait until your capsule are finished before seeing your doctor.

If you forget to take Lotense

Do not worry. If you forget to take a capsule, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a missed dose.

If you use too much

Taking too many capsules at once may make you unwell. If you take too many Lotense capsules contact your doctor at once or go to the nearest hospital casualty department.

If you stop using Lotense

Your doctor will advise you how long to take your medicine. Your condition may return if you stop using your medicine before you are advised.

If you have any further questions on how to take this product, ask your doctor or pharmacist.

6. WHILE YOU ARE USING LOTENSE

Things you must do

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Things to be careful of

Pregnancy

If you think you might be pregnant, or are planning to get pregnant, tell your

doctor before you take Lotense.

Women of child bearing potential should ensure that they use effective contraception.

Breast-feeding

You should not take Lotense if you are breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

7. SIDE EFFECTS

Lotense may cause the following side effects. Most side effects are mild or moderate:

- headache
- swelling of your legs or ankles
- tiredness, extreme sleepiness
- stomach pain, nausea
- dizziness
- flushing (hot or warm feeling in your face)
- heart palpitations (very fast heartbeat)

Tell your doctor if you are concerned about any side effects you experience. These are not all the possible side effects of Lotense. For a complete list, ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (consumers->reporting)

8. STORAGE AND DISPOSAL OF LOTENSE

Keep out of the reach and sight of children.

Do not store above 25°C.

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

Medicines should not be disposed of via wastewater of household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

9. PRODUCT DESCRIPTION

What it looks like

Lotense 5 mg: A white to off-white powder, rich yellow cap and white body size '3' hard gelatin capsules.

Lotense 10 mg: A white to off-white powder, light grey cap and light grey body size '3' hard gelatin capsules.

Ingredients

Active ingredient: amlodipine

The capsules contain amlodipine besylate equivalent to 5 mg amlodipine.

The capsules contain amlodipine besilate equivalent to 10 mg amlodipine.

Inactive ingredients

Microcrystalline cellulose, starch maize, magnesium stearate.

Registration Number

Product Name Registration Number

Lotense 5 mg

MAL10120005A

Lotense 10 mg

MAL10120004A

10. MANUFACTURER

Tabuk Pharmaceutical
Manufacturing Company
P.O. Box 3633,
Tabuk, Saudi Arabia.

PRODUCT REGISTRATION

HOLDER

Averroes Pharmaceuticals Sdn Bhd,
11E, Level 5, Block 1,
Worldwide Business Centre,
Section 13, 40000, Shah Alam,
Selangor.

11. DATE OF REVISION

2 August 2013