

Lotense®

Amlodipine Capsules

Composition:

Each capsule contains Amlodipine besylate equivalent to Amlodipine 5 mg.

Excipients: Starch, cellulose, magnesium Stearate.

Properties:

Lotense is a vasodilator, hypotensive medicine.

Amlodipine is a calcium ion influx inhibitor (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ion into cardiac and smooth muscle without changing serum calcium concentrations.

Its anti-hypertensive mechanism of action is due to a direct relaxant effect on vascular smooth muscle.

The mechanism by which amlodipine relieves angina is not yet fully determined.

After oral administration, amlodipine is absorbed with peak blood levels between 6-12 hours post dose, the oral bioavailability is about 64%, the terminal plasma elimination half life is about 30-50 hours.

Amlodipine is extensively metabolized by the liver with 90% converted to inactive metabolite.

10% of the parent compound and 60% of the metabolites are excreted in the urine.

Indications:

Lotense is indicated for:

Hypertension: Amlodipine besylate is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensives agents.

Chronic Stable Angina: Amlodipine besylate is indicated for the treatment of chronic stable angina. Amlodipine besylate may be used alone or in combination with other antianginal agents.

Vasospastic Angina (Prinzmetal's or Variant Angina):

Amlodipine besylate is indicated for the treatment of confirmed or suspected vasospastic angina. Amlodipine besylate may be used as monotherapy or in combination with other antianginal drugs.

Contraindications:

Lotense is contraindicated for patients with known hypersensitivity to any of its component.

In case of unstable angina, radiogenic shock and significant aortic stenosis.

Precautions:

Caution should be taken in case of pregnancy or lactation because safety has not been established.

Interactions with other drugs:

Lotense may be taken with thiazide diuretics, beta blockers, angiotensin converting enzyme inhibitors, long acting nitrates, sublingual nitroglycerine, non-steroidal anti-inflammatory drugs, antibiotics, and oral hypoglycemic medicines.

Warnings:

Elderly patients may have higher plasma concentration of amlodipine than those in the younger so they should start on a lower dose.

In patients with sever renal impairment, amlodipine dose may be need to be reduced.

Amlodipine half life is prolonged in patients with impaired liver function, therefore **Lotense** Should be administered at lower initial dose in these patients.

Dosage and Administration:

The usual initial dose for both hypertension and angina is:

5 mg once daily which may be increased to a maximum of 10 mg depending on the patient's response after 10-14 days therapy.

There is no need for dosage adjustment during combined administration of thiazide diuretics, beta blockers, or angiotensin converting enzyme inhibitor.

Overdosage:

No overdosage symptoms have been reported.

Gross overdosage could result in excessive peripheral vasodilation with subsequent marked and probably prolonged systemic hypotension.

Side Effects:

Headache, oedema, fatigue, somnolence, nausea, flushing, palpitations, dizziness, vomiting and abdominal pain.

Consult your pharmacist or physician if any side effect is observed.

Pharmaceutical Precautions:

Keep at room temperature (15-30 °C).

Do not use beyond the expiry date or if the product shows any visible sign of deterioration.

Presentation:

Pack of 30 Capsules.

Hospital packs are available.

® is a trademark.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.



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