

AMLO-US 10

Amlodipine Tablets

Composition:

Each uncoated tablet contains:
Amlodipine Besylate BP
Equivalent to Amlodipine 10 mg
Excipients q.s.

Therapeutic Indications

Hypertension
Chronic stable angina pectoris
Prinzmetal's angina

Dosage and Method of Administration

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

No dose adjustment of Amlodipine is required following concomitant administration with thiazide diuretics, beta-blockers, or angiotensin-converting enzyme inhibitors.

Method of administration:

Tablet for oral administration.

Contraindications:

Amlodipine is contraindicated in patients with:
hypersensitivity to dihydropyridine derivatives or amlodipine;
severe hypotension; shock (including cardiogenic shock); obstruction of the left ventricular outflow tract (e.g., high-grade aortic stenosis); hemodynamically unstable heart failure following acute myocardial infarction.

Warnings and special precautions for use:

The safety and efficacy of amlodipine in hypertensive crisis have not been established.

Interaction with other medicinal products and other forms of interaction:

Effects of other medicinal products on amlodipine

Concomitant use of amlodipine with strong or moderate CYP3A4 inhibitors (protease inhibitors, azole antifungals, macrolides such as erythromycin or clarithromycin, verapamil, or diltiazem) may result in a significant increase in amlodipine exposure, leading to an increased risk of hypotension.

Administration of amlodipine with grapefruit or grapefruit juice is not recommended, as bioavailability may be increased in some patients, resulting in an increase in blood pressure-lowering effects.

Effects of amlodipine on other medicinal products

The blood pressure-lowering effects of amlodipine add to the blood pressure-lowering effects of other medicinal products with antihypertensive properties.

In clinical interaction studies, amlodipine did not affect the pharmacokinetics of atorvastatin, digoxin, or warfarin.

Fertility, Pregnancy, and Lactation

Pregnancy

Use during pregnancy is recommended only when there is no safer alternative and when the disease itself poses a greater risk to the mother and the fetus.

Breastfeeding

It is not known whether amlodipine is excreted in breast milk. The decision to continue or discontinue breastfeeding, or to discontinue amlodipine therapy, should be made taking into account the benefit of breastfeeding to the child and the benefit of amlodipine therapy to the mother.

Fertility

Reversible biochemical changes in the head of the spermatozoa have been reported in some patients treated with calcium channel blockers.

Adverse Effects

The adverse reactions most frequently reported during treatment are somnolence, dizziness, headache, palpitations, flushing, abdominal pain, nausea, ankle swelling, edema, and fatigue.

Overdose

Experience with intentional overdose in humans is limited.

Excessive dosing may result in excessive peripheral vasodilation and possibly reflex tachycardia. Marked and likely prolonged systemic hypotension—up to and including shock with a fatal outcome—has been reported.

Since amlodipine is highly protein-bound, dialysis is unlikely to be beneficial.

Storage: Store below 30°C in a dry place. Protect from light.

Keep medicines out of the reach of children.

Presentation: Box containing 10 blisters of 10 tablets, together with the package insert.

Manufactured by:

