

AMLOc

SCHEDULING STATUS [S]

1. NAME OF THE MEDICINE

AMLOc 5 mg tablets

AMLOc 10 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each AMLOc 5 mg tablet contains amlodipine mesilate equivalent to amlodipine 5 mg. Each AMLOc 10 mg tablet contains amlodipine mesilate equivalent to amlodipine 10 mg. AMLOc tablets are sugar free.

Essentially sodium free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets  
AMLOc 5 mg: A white, round, slightly biconvex, bevelled edge tablet, scored on one side. Diameter: 8.0 mm.  
AMLOc 10 mg: A white, round, slightly biconvex, bevelled edge tablet, scored on one side. Diameter: 10.0 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

AMLOc is indicated for the treatment of mild to moderate hypertension, alone or in combination with other antihypertensives.

4.2 Pharmacokinetics

AMLOc is indicated for the treatment of mild to moderate hypertension, alone or in combination with other antihypertensives.

4.3 Contraindications

AMLOc is contraindicated in:  
• patients with known hypersensitivity to any of the ingredients of AMLOc  
• stroke, including cerebrovascular stroke  
• haemodynamically unstable heart failure after acute myocardial infarction (during the first 28 days)  
• unstable angina pectoris  
• should not be used for acute reduction of blood pressure  
• severe hypotension  
• severe liver impairment  
• obstruction of the outflow tract of the left ventricle (e.g. high grade aortic stenosis).

4.4 Special warnings and precautions for use

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

4.5 Concomitant therapy with potent cytochrome CYP3A4 inhibitors

Potent CYP3A4 inhibitors such as ketoconazole, itraconazole or ritonavir, may enhance the blood pressure lowering effect of AMLOc when taken together (see section 4.5).

4.6 Use in the elderly

The time to reach peak plasma concentrations of AMLOc is variable and not significantly different between elderly and younger subjects. AMLOc may increase the risk of developing heart failure in patients with severe aortic stenosis. AMLOc should be used with caution in patients with congestive heart failure, as it may increase the risk of future cardiovascular events and mortality.

4.7 Use in renal failure

AMLOc has not been studied primarily in the kidney, mild renal impairment does not appear to have an effect on the plasma concentrations. Severe renal impairment may however require a dosage reduction. Amlodipine is not dialysable.

4.8 Use in hepatic failure

AMLOc should be stopped in patients who have ischaemic pain after use.

4.9 Information on excipients of AMLOc

AMLOc contains sodium. AMLOc contains less than 1 mmol (0.023 g) sodium per tablet, that is to say essentially sodium free.

4.10 Use in pregnant women

AMLOc should be used with caution in patients with hypertension.

4.11 Use in lactating women

AMLOc should be used with caution in patients with hypertension.

4.12 Diabetes mellitus

AMLOc should be used with caution in patients with hypertension.

4.13 Interference with diagnostic tests

AMLOc should be used with caution in patients with hypertension.

4.14 Effects of other medicines on AMLOc

AMLOc should be used with caution in patients with hypertension.

4.15 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.16 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.17 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.18 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.19 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.20 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.21 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.22 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.23 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.24 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.25 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.26 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.27 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.28 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.29 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.30 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.31 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.32 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.33 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.34 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.35 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.36 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.37 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.38 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.39 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.40 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.41 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.42 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.43 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.44 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

Diagnosis

In healthy volunteers, neither serum digoxin levels nor renal clearance were changed when digoxin was co-administered with AMLOc.

Enthalal (Amlodipine)

Enthalal (Amlodipine) 10 mg doses of AMLOc had no significant effect on the pharmacokinetics of enthalal. Shape and margin: 10 mg doses of AMLOc had no significant effect on the pharmacokinetics of enthalal.

Warfarin

Co-administration of AMLOc with warfarin did not change the warfarin pharmacokinetic response time.

Antidiabetic medicines

Concurrent administration of sublingual nifedipine, long-acting nifedipine, or other antidiabetic medicines with AMLOc did not affect the plasma glucose levels or the hypoglycaemic response to insulin. AMLOc may be used as needed to treat diabetic angina attacks during AMLOc therapy; insulin administration may be used during AMLOc therapy for angina prophylaxis.

4.6 Fertility, pregnancy and lactation

AMLOc can have minor or moderate influence on the ability to drive and use machines. AMLOc can cause side effects such as dizziness, headache, fatigue, or nausea and their ability to react may be impaired. During AMLOc administration, patients should be cautioned about driving a vehicle or operating machinery.

4.7 Effects on ability to drive and use machines

AMLOc can have minor or moderate influence on the ability to drive and use machines. AMLOc can cause side effects such as dizziness, headache, fatigue, or nausea and their ability to react may be impaired. During AMLOc administration, patients should be cautioned about driving a vehicle or operating machinery.

4.8 Concomitant therapy with potent cytochrome CYP3A4 inhibitors

Potent CYP3A4 inhibitors such as ketoconazole, itraconazole or ritonavir, may enhance the blood pressure lowering effect of AMLOc when taken together (see section 4.5).

4.9 Use in the elderly

The time to reach peak plasma concentrations of AMLOc is variable and not significantly different between elderly and younger subjects. AMLOc may increase the risk of developing heart failure in patients with severe aortic stenosis. AMLOc should be used with caution in patients with congestive heart failure, as it may increase the risk of future cardiovascular events and mortality.

4.10 Use in renal failure

AMLOc has not been studied primarily in the kidney, mild renal impairment does not appear to have an effect on the plasma concentrations. Severe renal impairment may however require a dosage reduction. Amlodipine is not dialysable.

4.11 Use in hepatic failure

AMLOc should be stopped in patients who have ischaemic pain after use.

4.12 Information on excipients of AMLOc

AMLOc contains sodium. AMLOc contains less than 1 mmol (0.023 g) sodium per tablet, that is to say essentially sodium free.

4.13 Use in pregnant women

AMLOc should be used with caution in patients with hypertension.

4.14 Use in lactating women

AMLOc should be used with caution in patients with hypertension.

4.15 Diabetes mellitus

AMLOc should be used with caution in patients with hypertension.

4.16 Interference with diagnostic tests

AMLOc should be used with caution in patients with hypertension.

4.17 Effects of other medicines on AMLOc

AMLOc should be used with caution in patients with hypertension.

4.18 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.19 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.20 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.21 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.22 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.23 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.24 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.25 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.26 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.27 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.28 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.29 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.30 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.31 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.32 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.33 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.34 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.35 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.36 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.37 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.38 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.39 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.40 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.41 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.42 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.43 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.44 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.45 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.46 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.47 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.48 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.

4.49 Effects of AMLOc on other medicines

AMLOc should be used with caution in patients with hypertension.



