

1.1 – Summary of Products Characteristics (SmPC)

APPEARANCE: White octagonal tablet embossed with 5 on one side and imprint of CDL on the other side representing Cardinal Drugs Limited.

COMPOSITION: Each tablet contains Amlodipine Besylate equivalent to Amlodipine 5mg.

Amlodipine Besylate is chemically: (RS)-3-ethyl 5-methyl 2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate

EXCIPIENT: Corn Starch, Gelatin, Aerosil, Avicel, Methyl Paraben, Propyl Paraben, Magnesium Stearate.

PROMOTIONAL CATEGORY: Prescription Only Medicine (POM)

INDICATIONS: Amlodipine is used in the management of hypertension and angina.

PRESENTATION AND PACKAGING:

A monocardon containing two strips of blister pack of 14 tablets (i.e 2 x 14)

ROUTE OF ADMINISTRATION: Oral

DOSAGE:

As prescribed by your physician

DOSAGE FORM: It is Tablet per oral

SIDE EFFECTS: Side effects which are dose dependent of Amlonac include vasodilatory effects, peripheral oedema, dizziness, palpitations, and flushing.

Common but not dose-related side effects are fatigue, nausea, drowsiness and abdominal pain.

CONTRA-INDICATION: Allergic to amlodipine or other dihydropyridines. In people with cardiogenic shock. It can cause collapse in cases of severe stenosis.

PRECAUTIONS: Amlodipine's safety in pregnancy has not been established, although reproductive toxicity at high dose is known. Whether amlodipine enters the milk of breastfeeding mothers is also unknown.

ANTIDOTE: Toxicity is generally managed with fluid replacement. Vasopressors are also administered when low blood pressure is not alleviated by fluid resuscitation.

TERATOGENICITY:

Pregnancy

Amlodipine's safety in pregnancy has not been established, although reproductive toxicity at high dose is known.

Breastfeeding

Whether amlodipine enters the milk of breastfeeding mothers is also unknown.

SHELF LIFE: 3 years

STORAGE: Store below 30°C, in a dry place. Protect from direct sunlight.