

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

Cardinol 25 mg Film Coated Tablets

2. Qualitative and quantitative composition

Each film coated tablet contains Atenolol 25 mg.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Film coated tablet.

Orange circular biconvex film coated tablet embossed COSMOS on one side and a breakline on the other side.

4.1 Therapeutic indications

Cardinol (atenolol) is indicated for the management of hypertension, angina pectoris, cardiac arrhythmias, and for secondary prevention following myocardial infarction.

4.2 Posology and method of administration

Dosage should be individualised based on patient response. Tablets should be swallowed whole with water, preferably in the morning.

4.3 Contraindications

Hypersensitivity to atenolol, bronchial asthma, uncontrolled heart failure, cardiogenic shock, metabolic acidosis, and second- or third-degree heart block.

4.4 Special warnings and precautions for use

Beta-blockers should not be withdrawn abruptly. Caution is advised in patients with diabetes, peripheral vascular disease, and first degree heart block.

4.5 Fertility, pregnancy and lactation

Atenolol should not be used during pregnancy and breastfeeding unless clearly necessary.

4.6 Effects on ability to drive and use machines

May cause dizziness or fatigue. Patients should exercise caution.

4.8 Undesirable effects

The following adverse reactions have been reported with atenolol: bradycardia, fatigue, cold extremities, gastrointestinal disturbances, dizziness, and headache.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via the National Regulatory Authority. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued

monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>

5. Pharmacological properties

Atenolol is a cardioselective beta-1 adrenergic blocker (ATC Code: C07AB03).

6.1 List of excipients

Light magnesium carbonate BP; Maize starch BP; Sodium lauryl sulphate BP; Gelatin BP; Magnesium stearate BP; Carnauba wax NF; Opadry QX; Lake of sunset yellow; Ponceau 4R lake.

6.3 Shelf life

3 years.

7. Marketing Authorisation Holder

Cosmos Limited, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER(S)

8068

9 DATE OF FIRST APPROVAL**10 DATE OF REVISION**

14 July 2026