Summary of product Characteristics (SmPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

CARDIOTEN-50 (Atenolol Tablets BP 50 mg)

1.1 Strength

50 mg

1.2 Pharmaceutical form

Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Atenolol BP……50 mg

3.PHARMACEUTICAL FORM

Tablets (Oral)CARDIOTEN-50 (Atenolol Tablets BP 50mg) Tablets are presented as Orange Circular Biconvex coated tablets embossed "ATEN 50" on one side and plain on other side, without any visible defects.

4.CLINICAL PARTICULARS

4.1 Therapeutic indications:

Atenolol is indicated in the management of Hypertension, Angina pectoris, Cardiac arrhythmias and for reducing the risk of mortality and non-fatal reinfarction in survivors of acute myocardial infarction.

4.2 Posology and method of administration:

Administration via oral route.To be taken with glass of water. The recommended dosage of Atenolol is as follows: Hypertension- 50mg daily
Angina- 100mg daily in 1 or 2 doses Arrhythmias- 50mg to 100mgdailyMyocardial infarction: Early intervention within 12 hours, by intravenous injection 5mg over 5 minute, followed by 5mg over 10 minutes; then by mouth 50ng twice daily during hospitalization. After hospitalization 50mg daily for 1-3 years.
Renal impairment- Reduced dosage considering severity of impairment CARDIOTEN tablets are not recommended for use in children.

4.3 Contraindications:

Atenolol is contraindicated in patients with sinus bradycardia, heart block greater than first degree, cardiogenic shock, overt cardiac failure, anuria,

asthma, metabolic acidosis, Prinzmetal's angina, phaeochromocytoma, hypersensitivity to Atenolol.

4.4 Special warnings and precautions for use:

Atenolol therapy should not be withdrawn abruptly to prevent exacerbation of angina pectoris, rebound hypertension, myocardial infarction, ventricular arrhythmias and sudden cardiac death. Treatment should be discontinued over one to two weeks.
Use with caution in patients having congestive cardiac failure controlled by digitalis and/or diuretics. Use atenolol with caution in patients with Prinzmetal's angina, patients with poor cardiac reserve and those experiencing peripheral arterial circulatory disturbances,
bronchospastic diseases, first degree AV-block and in diabetic patients with hepatic and renal impairment. Atenolol may mask the signs of thyrotoxicosis and symptoms of hypoglycaemia (I particular tachycardia).

4.5 Interactions with other medicinal products and other forms of interactions

Atenolol should not be given together with verapamil/diltiazem or within 48 hours of discontinuing treatment and vice versa.
Catecholamine depleting drugs (eg. Reserpine), calcium channel blockers (eg. Verapamil, Nifedipine & Diltiazem) and class I antiarrhythmic drugs (eg. Disopyramide & Amiodarone) may have an additive effect when given with beta-blockers like atenolol. This may result in severe hypotension, bradycardia and cardiac failure. Some second-generation antihistamines, notably terfenadine and astemizole, have been associated with prolongation of the QT interval and the development of torsades de pointes, a potentially fatal ventricular arrhythmia. Concomitant administration with atenolol should be avoided.
THE ABOVE DRUG-DRUG INTERATION ARE LIFE THREATNING AND POTENTIALLY FATAL.

Concomitant therapy of atenolol with clonidine, sympathimimetic agents (eg. Adrenaline) and anaesthetic agents causing myocardial depression, is contraindicated. Co-administration of atenolol with oral antodiabetics (eg. Glibenclamide & Repaglinide). Ergot alkaloids (eg. Ergotamine and derivatives) may potentiate the effect of beta-2-adrenoceptors (eg. Salbutamol & Terbutaline) Leading to exacerbation of asthma symptoms. Concomitant use of prostaglandin synthase inhibiting drugs (eg. Indomethacin & Ibuprofen) may decrease the hypotensive effect of atenolol.

4.6 Fertility, Pregnancy and lactation

Cautions should be exercised when Atenolol is administered during pregnancy or to a woman who is breat-feeding.

4.7 Effects on ability to drive and use machines

None expected at recommended doses and duration of therapy.

4.8 Undesirable effects

Atenolol is usually well tolerated and adverse drug reactions are uncommon, most of which are mild and transient. Atenolol may cause bradycardia, hypotension, heart failure, cold extremities, gastro-intestinal disturbances, psoriasis, myasthenia gravis, leg pain, dizziness, vertigo, light headedness, nightmares, diarrhea, nausea, wheeziness and dyspnoea. Peripheral arterial circulatory disturbances (Raynauds's phenomenon) leading to gangrene have also been reported. Miscellaneous reactions include skin rashes, dry eyes.

Reporting of suspected adverse reactions
Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board,Pharmacovigilance Electronic Reporting System (PvERS)
https://pv.pharmacyboardkenya.org

4.9 Overdose

Effects can include bradycardia, cardiac conduction block, hypotension, heart failure and cardiogenic shock. Convulsions, coma, Bronchospasm, respiratory, depression and bronchoconstriction can also occur although infrequently. Treatment: Bradycardia associated with severe hypotension should be treated with atropine intravenously followed by a slow infusion of isoprenaline/glucagon if necessary. Cardiogenic shock unresponsive to atropine is probably best treated with an intravenous injection of glucagon.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Anti-hypertensive **ATC code:** C07AB03
Mechanism of Action

Atenolol is a β_1-selective (Cardioselective) beta-adrenengic receptor blocking agent without membrane stabilizing or intrinsic sympathomimetic (Partial agonistic) activities. This preferential effect, is not absolute, however, and at higher doses, Atenolol β inhibits- adrenoreceptors, chiefly located in the bronchial and vascular musculature.
In standard animal or human pharmacological experiments β – adrenoreceptor blocking activity of Atenolol has been demonstrated by (1) reduction in resting and exercise heart rate and cardiac output, (2) reduction of systolic and diastolic blood pressure at rest and on exercise, (3) inhibition of isoproterenol induced tachycardia, and (4) reduction in reflux orthostatic tachycardia. By blocking the positive chronotropic and ionotropic effects of catecholamines and by decreasing blood pressure, Atenolol generally reduces oxygen requirements of the heart at any given level of effort, making it useful for many patients in the long-term management of angina pectoris. Atenolol has also shown other clinical benefits including reduced frequency of ventricular premature beats, reduced chest pain and reduced enzyme elevation.
Upon oral administration, Atenolol is incompletely (50%) but rapidly absorbed

from the gastrointestinal tract. Peak blood levels are reached between 2 and 6 hours after dosing. There is no significant hepatic metabolism of Atenolol and more than 90% of that absorbed reaches the systemic circulation unaltered. Atenolol penetrates tissues poorly due to its low lipid solubility and its concentration in brain tissue is low.
Plasma protein binding is low. Atenolol is primarily eliminated by renal excretion. The elimination half-life is 6 to 7 hours. Following doses of 50mg or 100mg, both beta blocking and antihypertensive effects persist for at least 24 hours.

5.2 Pharmacokinetic properties

Absorption

Absorption of atenolol following oral dosing is consistent but incomplete (approximately 40- 50%) with peak plasma concentrations occurring 2-4 hours after dosing. The atenolol blood levels are consistent and subject to little variability. There is no significant hepatic metabolism of atenolol and more than 90% of that absorbed reaches the systemic circulation unaltered.
Distribution

Atenolol penetrates tissues poorly due to its low lipid solubility and its concentration in brain tissue is low. Plasma protein binding is low (approximately 3%).
Elimination

The plasma half-life is about 6 hours but this may rise in severe renal impairment since the kidney is the major route of elimination.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to those already included in other sections. Non-clinical data reveal no special hazards for humans based on conventional studies of safety, pharmacology, repeat–dose toxicity or genotoxicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch

Lactose Monohydrate
Colloidal Silicon Dioxide
Microcrystalline Cellulose [PH101] Sodium Lauryl Sulphate
Povidone Pyrrolidone

Sodium Strach Glycollate Purified Talc
Stearic Acid
Magnesium Stearate
Hydroxypropyl Methyl Cellulose Dibutyl Phthalate
Titanium Dioxide

Colour Sunset Yellow Lake
Isopropyl Alcohol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months (3 Years)

6.4 Special precautions for storage

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

6.5 Nature and contents of container Primary Container: Alu/Pvc Blister Secondary Container: Paperboard carton

6.6 Special precautions for disposal and other handling

None

7. MARKETING AUTHORISATION HOLDER:

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8. Marketing authorization registration number(s).

10857

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

02/2019

10. DATE OF REVISION OF THE TEXT:

28/02/2026