SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

1.1 Brand Name	:	**Ateleb-50 Tablet**
1.2 Generic Name	:	**Atenolol Tablet BP 50mg.**
1.3 Strength	:	**50mg/Tablet**
1.4 Pharmaceutical Form	:	**Tablet**

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Each uncoated tablet contains:

Atenolol BP 50 mg

3. PHARMACEUTICAL FORM

Tablet

White coloured round shaped, biconvex, uncoated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Atenolol **(Ateleb)** is indicated in the treatment of Hypertension, Angina and Arrhythmias.

4.2 Posology and method of administration

Hypertension: Adult: 50-100 mg daily higher doses are rarely necessary.

Angina: Adult: 100 mg daily in 1–2 divided doses.

Arrhythmias: Adult: 50–100 mg daily.

4.3 Contraindications

Atenolol, as with other beta-blockers, should not be used in patients with any of the

following: Cardiogenic shock, Uncontrolled heart failure, Sick sinus syndrome (including sino-atrial block), Second-or third-degree heart block, Untreated pheochromocytoma, Metabolic acidosis, Bradycardia, Hypotension, Severe peripheral arterial circulatory disturbances, Severe asthma and severe chronic obstructive pulmonary disorders, such as airway obstructions.

4.4 Special warnings and special precautions for use

Atenolol as with other beta-blockers: Should not be withdrawn abruptly. The dosage should be withdrawn gradually over a period of 7–14 days, to facilitate a reduction in beta-blocker dosage. Patients should be followed during withdrawal, especially those with ischaemic heart disease.

Renal Impairment: Dose adjustments with oral use Max. 50 mg daily if eGFR 15-35mL/minute/1.73m^2; max. 25mg daily or 50mg on alternate days if eGFR less than 15 mL/minute/1.73 m^2.

Important Safety Information Safe Practice: Atenolol has been confused with amlodipine; care must be taken to ensure the correct drug is prescribed and dispensed.

4.5 Interaction with other FPPs and Other forms of Interaction

Beta blockers, selective are predicted to increase the risk of bronchospasm when given with aminophylline. Antiarrhythmics (amiodarone, disopyramide, dronedarone, flecainide, lidocaine) are predicted to increase the risk of cardiovascular side-effects when given with beta blockers, selective. Anticholinesterases, centrally acting are predicted to increase the risk of bradycardia when given with beta blockers, selective. Mefloquine is predicted to increase the risk bradycardia when given with beta blockers, selective. Oral calcium channel blockers (verapamil) increase the risk of cardiovascular side-effects when given with beta blockers, selective.

4.6 Pregnancy and lactation

Atenolol crosses the placental barrier and appears in the cord blood. Administration of Atenolol to pregnant women in the management of mild to moderate hypertension has been associated with intra-uterine growth retardation. In case of Breast Feeding Water soluble beta-blockers such as atenolol are present in breast milk in greater amounts than other beta blockers. Thus should be avoided in case of breast Feeding. It is only recommended for use during pregnancy when there are no alternatives and benefit outweighs risk.

4.7 Effects on ability to drive and use machines

Use is unlikely to result in any impairment of the ability of patients to drive or operate machinery. However, it should be taken into account that occasionally dizziness or fatigue may occur.

4.8 Undesirable effects

Common or very common: Gastrointestinal disorder.

Rare or very rare: Mood altered, psychosis.
Frequency not known: Hypersensitivity. Lupus-like syndrome.
Specific Side-Effects: Rare or very rare: Hepatic disorders.

4.9 Overdose & Treatment

The symptoms of overdosage may include bradycardia, hypotension, acute cardiac insufficiency and bronchospasm. General treatment should include: close supervision; treatment in an intensive care ward; the use of gastric lavage; activated charcoal and a laxative to prevent absorption of any drug still present in the gastrointestinal tract.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Anti-hypertensive
ATC Code: C07AB03
Mechanism of action: Atenolol work by selectively binding to the beta-1 adrenergic receptors found in vascular smooth muscle and the heart, blocking the positive inotropic and chronotropic actions of endogenous catecholamines such as isoproterenol, norepinephrine, and epinephrine, thereby inhibiting sympathetic stimulation. This activity results in a reduction in heart rate, blood pressure, and decreases myocardial contractility.

5.2 Pharmacokinetic properties

Absorption of Atenolol following oral dosing is consistent but incomplete (approximately 40–50%) with peak plasma concentrations occurring 2–4 hours after dosing. The bioavailability is decreased by 20% when taken with food. The protein binding is low (approximately 3%). Most of an absorbed dose (85-100%) is excreted unchanged via the urine. The clearance is about 6 l/h and the half-life is about 6 to 9 hours.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name of Excipients	Spec.
Dibasic Calcium Phosphate	BP
Starch (Maize)	BP
Microcrystalline Cellulose	BP
Sodium Lauryl Sulfate	BP
Microcrystalline Cellulose (102)	BP
Purified Talc (Talcum)	BP
Magnesium Stearate	BP

Name of Excipients	Spec.
Colloidal Anhydrous Silica (Colloidal Silicon Dioxide)	BP
Sodium Starch Glycolate	BP
Purified Water	BP

6.2 Incompatibilities

No sufficient data is available

6.3 Shelf life

36 months from the date of manufacturing.

6.4 Special precautions for storage

Protect from light. Keep away from moisture. Keep out of reach of children. Store at a temperature not exceeding 30°C.

6.5 Nature and contents of container

10 blisters of 10 tablets packed in an inner carton (10x10).
1000 tablets packed in white coloured HDPE jar (1000's).

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

09521/10465/NMR/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Mar 11, 2024

10. DATE OF REVISION OF THE TEXT

01/01/2028