1. Name of the medicinal Product

Atenolol Tablets BP

1.1 Strength

100 mg/tablet

1.2 Pharmaceutical Form

Oral Tablets

2. Qualitative and Quantitative Composition

2.1 Qualitative declaration

Atenolol BP

2.2 Quantitative declaration

Sr. No	Ingredients Chemical Name	Specification	Quantity (mg/tablet)	Reason for Inclusion
1	Atenolol	BP	100.0	Beta Adrenoreceptor Antagonist
2	Microcrystalline Cellulose (Plain)	BP	54.16	Diluent
3	Maize Starch	BP	77.42	Diluent
4	Maize Starch	BP	10.75	Binder
5	Purified water (#)	BP	Q.S.	Solvent
6	Maize Starch	BP	39.00	Disintegrating agent
7	Microcrystalline Cellulose (Plain)	BP	25.00	Diluent
8	Sodium Starch Glycolate (Type-A)	BP	20.00	Disintegrating agent
9	Colloidal Anhydrous Silica (Aerosil)	BP	4.000	Glidant
10	Magnesium Stearate	BP	5.000	Lubricant
11	Purified Talc	BP	3.000	Glidant

3. Pharmaceutical Form

Oral Tablets

White to off-white coloured, round shaped, biconvex, uncoated tablets having breakline on one side & plain on other side.

4. Clinical Particulars

4.1 Therapeutic Indications

It is indicated in patients for the management of hypertension, angina pectoris and cardiac dysrhythmias & for early intervention in the acute phase of myocardial infarction.

4.2 Posology

Adults:

Hypertension: The initial dose of Atenolol is 50 mg given as one tablet a day either alone or added to diuretic therapy. I fan optimal response is not achieved, the dosage should be increased to l00 mg given as two tablets a day.

Angina Pectoris: The initial dose is 50 mg given as one tablet a day. If an optimal response is not achieved within one week, the dosage should be increased to 100 mg once a day. Some patients may require a dosage of 200 mg once a day for optimal effect.

Acute Myocardial Infarction: In patients who tolerate the full intravenous dose (10 mg), 50 mg should be initiated 10 minutes after the last intravenous dose followed by another 50 mg oral dose 12 hours later. Thereafter, it can be given orally either 100 mg once daily or 50 mg twice a day for a further 6-9 days or until discharge from the hospital**.**

Children under 12 years of age:

There are inadequate clinical data available on the use of atenolol in children and forth is reason it is not recommended**.**

4.3 Method of Administration

Oral Route

4.4 Contraindications

Atenolol is contraindicated in Second or third degree heart block, Cardiogenic shock, Uncontrolled heart failure, Sick sinus syndrome (including sino-atrial block), Untreated phaeochromocytoma, Metabolic acidosis, Bradycardia (less than 45-50 beats per minute), Hypotension, Hypersensitivity to atenolol or any of the Excipients, Severe peripheral circulatory disturbances.

4.5 Special Warnings and Special Precautions for Use

Precaution should be taken in patients already on a beta blocker, phaeochromocytoma, asthma, bronchitis and other chronic pulmonary diseases, impaired renal function, arterial circulatory disorders, Raynaud's phenomenon. Caution should be exercised in pregnancy, Nursing Mothers and elderly patient. Discontinuation of therapy should be gradual.

Pregnancy: It crosses the placental barrier and appears in the cord. It has been used under close supervision for the treatment of pregnancy-associated hypertension in the third trimester. Administration of atenolol to pregnant women in the management of mild to moderate hypertension has been associated with intra-uterine growth retardation. Caution should be exercised in pregnancy.

Lactation: There is significant accumulation of atenolol in breast milk. Neonates born to mothers who are receiving atenolol at parturition or breast-feeding may be at risk for hypoglycemia and bradycardia. Caution should be exercised in elderly patient. Discontinuation of therapy should be gradual.

4.6 Paediatric Population

Children:

There are inadequate clinical data available on the use of atenolol in children and forth is reason it is not recommended**.**

4.7 Interaction with other medicinal products and other forms of interaction

Calcium channel blockers and Catecholamine-depleting drugs an additive effect with atenolol. If atenolol and clonidine are given concurrently the clonidine should not be discontinued until several days after the withdrawal of the atenolol as severe rebound hypertension may occur. Concomitant use of prostaglandin synthase inhibiting drugs.

4.8 Additional information on special populations

No specific Information

4.9 Paediatric Population

No specific Information

4.10 Pregnancy and Lactation

4.10.1 Pregnancy

It crosses the placental barrier and appears in the cord. It has been used under close supervision for the treatment of pregnancy-associated hypertension in the third trimester. Administration of atenolol to pregnant women in the management of mild to moderate hypertension has been associated with intra-uterine growth retardation. Caution should be exercised in pregnancy.

4.10.2 Lactation

There is significant accumulation of atenolol in breast milk. Neonates born to mothers who are receiving atenolol at parturition or breast-feeding may be at risk for hypoglycemia and bradycardia. Caution should be exercised in elderly patient. Discontinuation of therapy should be gradual.

4.11 Effects on ability to Drive and use Machines

As with all beta-blockers it is not likely to affect your ability to drive or to use machines. However, it is best to wait and see how your medicine affects you before trying these activities. If you feel dizzy or tired when taking this medicine, do not drive or use any tools or machines.

4.12 Undesirable Effects

The most common side-effects arc nausea, vomiting, diarrhoea, fatigue and dizziness. Cardiovascular effects include bradycardia, congestive heart failure, heart block, hypotension, cold extremities, Raynaud's phenomenon and parasthesia. Central nervous system effects include depression, hallucinations and disturbances of sleep (sleeplessness, nightmares) and vision.

4.13 Overdose

Acute doses as high as 5 gm. The predominant symptoms reported are lethargy, disorder of respiratory drive, wheezing, sinus pause and bradycardia. Additionally, common effects of over dosage are congestive heart failure, hypotension, bronchospasm and/or hypoglycemia.

Treatment of overdose should be directed to the removal of any unabsorbed drug by induced emesis, gastric lavage, or administration of activated charcoal, hemodialysis.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Atenolol is a cardia selective beta-blocker. The cardio-selectivity is dose related. Atenolol causes a reduction in blood pressure by lowering cardiac output, decreasing the plasma renin activity and sympathetic outflow from CNS. Atenolol also causes a reduction in myocardial oxygen demand by virtue of its negative ionotropic and negative chronotropic effects.

5.2 Pharmacokinetic Properties

Absorption of Atenolol following oral dosing is rapid & consistent but incomplete (approximately 40-50%) with peak plasma concentrations reached 2-4 hours after dosing. There is no significant hepatic metabolism of atenolol and more than 90% of that absorbed reaches the systemic circulation unaltered. 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. Atenolol penetrates tissues poorly due to its low lipid solubility and its concentration in brain tissue is low. Plasma protein binding is 6-16%.

5.3 Preclinical Safety Data

Not Applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

Microcrystalline Cellulose (Plain)
Maize Starch
Sodium Starch Glycolate (Type-A)
Colloidal Anhydrous Silica (Aerosil)
Magnesium Stearate
Purified Talc
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30°C. Protect from light.

6.5 Nature and Contents of Container

10 tablets are packed in Alu-Alu blister pack. Such 10 Alu-Alu blister packs are packed in a printed carton along with package insert.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses

7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com;
Web site: www.lincolnpharma.com

7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com;
Web site: www.lincolnpharma.com

8. Marketing Authorization Number

Rwanda FDA-HMP-MA-0292

9. Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

10. Date of Revision of the Text

May,2023

11. Dosimetry (If Applicable)

Not Applicable

12. Instructions for preparation of radiopharmaceuticals

Not Applicable