

PATIENT INFORMATION LEAFLET
(ANOL-50 /100) ATENOLOL BP TABLETS 50 MG/ 100 MG
[Atenolol BP]

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others.

It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. What Atenolol Tablets is and what it is used for
2. Before you use Atenolol Tablets
3. How to use Atenolol Tablets
4. Possible side effects
5. How to store Atenolol Tablets
6. Further information

1. WHAT ATENOLOL TABLETS IS AND WHAT IT IS USED FOR

It contains active ingredient atenolol, medicines known as Beta adrenoreceptor antagonist. It is a cardio selective beta-blocker. The cardio-selectivity is dose-related. It 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 inotropic and negative chronotropic effects. 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.

2. BEFORE YOU USE ATENOLOL TABLETS

It is contraindicated in patient history of serious hypersensitivity to atenolol or to any of excipients. It is contraindicated in Second or third degree heart block, Cardiogenic shock, Uncontrolled heart failure, Sick sinus syndrome (including sino-atrial block), Untreated pheochromocytoma, Metabolic acidosis, Bradycardia (less than 45-50 beats per minute), Hypotension, Severe peripheral circulatory disturbances.

Take special care with atenolol tablets: Warnings and Precautions: Talk to your physician before taking atenolol tablets. Precaution should be taken in patients already on a beta blocker, pheochromocytoma, asthma, bronchitis and other chronic pulmonary diseases, impaired renal function, arterial circulatory disorders, Raynaud's phenomenon. Patients with hepatic impairment may need a lower dosage of atenolol. Atenolol is excreted via the kidneys, dosage adjustment should therefore be considered in patients with severe impairment of renal function. Patients with a serum creatinine of 300 - 600 µmol/L, the atenolol oral dose should be 50 mg daily or 100 mg once every two days, for patients with a serum creatinine of > 600 µmol/L, the oral dose of Atenolol should be 50 mg on alternate days or 100 mg once every four days. Patients on haemodialysis should be given 50 mg atenolol orally following each dialysis. Pediatrics: There is no pediatric experience with atenolol and for this reason it is not recommended for use in children.

Using other medicines: Tell your physician if you are taking 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. **Using Atenolol Tablets with food and drink:** It is advised to patient avoid use of alcohol whilst taking this medicines. **Pregnancy and breast-feeding:** Before taking any medicine for advice consult to direction of physician. Caution should be exercised when it is administered during pregnancy or to nursing women. **Pregnancy: 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. **Use in breast-feeding:** 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.

Driving and using 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. **Important information about some of the ingredients of atenolol tablets contains excipients with known effects:** None

3. HOW TO USE ATENOLOL TABLETS

It should be taken as directed by physician. Take your normal dose immediately and continue taking your tablets at the usual time of day, do not take a double dose to make up for the missed dose. Do not change your usual dose without talking to physician. **Method of administration:** *For oral use only.* It may be taken with or without food or as directed by physician. It should be swallowed with a glass of water. Dose must be individualize. Patients should be maintained on lower doses if higher doses are not tolerated.

The usual recommended doses: Adults: Hypertension: The initial dose of Atenolol is 50 mg given as one tablet a day either alone or added to diuretic therapy. If an optimal response is not achieved, the dosage should be increased to 100 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 for this reason it is not recommended. **If you more Atenolol tablets than you should:** If you accidentally take too many tablets, contact your physician immediately. 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.

If you forget to atenolol tablets: If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten tablet. If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. The most common side-effects are 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.

5. HOW TO STORE ATENOLOL TABLETS

Keep this medicine out of the sight and reach of children. Store below 30°C. Protect from light. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contain active substances as atenolol BP. Each uncoated tablet contains: atenolol BP 50 mg/100 mg. **Excipients:** microcrystalline cellulose, maize starch, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, purified talc. **Pack size:** White to off-white coloured, round shaped, biconvex, uncoated tablets having plain on both side, 10such tablets are packed in Alu-Alu Blister Pack. Such 10 Alu-Alu blisters are packed in a printed carton along with packing insert.

Manufactured by:

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.

Phone: +91-079-41078096

Telefax: +91-79-41078062

Email: hiren@lincolnpharma.com

Website: www.lincolnpharma.com

For any information about this medicinal product, please contact the local representative of the supplier:

Lincoln Pharmaceuticals Limited Trimul Estate, Khatraj, Taluka: Kalol, District: Gandhinagar Gujarat, India. Phone: +91-079-41078096 Telefax: +91-79-41078062 Email: hiren@lincolnpharma.com Website: www.lincolnpharma.com	Abacus Pharma (A) Ltd Kigali city market, B1-R85, PO Box 4344, Kigali, Rwanda. Phone: +91-079-41078096 Telefax: +91-79-41078062 Email: abacuspharmacist@gmail.com
--	---

Date of publication or revision

17.04.2023