(L)250mm

(W)200mm

pharmaniaga™

Atenolol

Tablet

DESCRIPTION

Pharmaniaga Atenolol tablet 50 mg

An orange, round, film-coated tablet with a breakline on one side and plain on the other.

Pharmaniaga Atenolol tablet 100 mg

An orange, round, film-coated tablet with a breakline on one side and Pharmaniaga icon on the other.

COMPOSITION

Pharmaniaga Atenolol tablet 50 mg

Each film-coated tablet contains Atenolol 50 mg.

Pharmaniaga Atenolol tablet 100 mg

Each film-coated tablet contains Atenolol 100 mg.

ACTIONS

Atenolol is a $beta_1$-selective (cardioselective) beta-adrenergic receptor blocking agent without membrane stabilising or intrinsic sympathomimetic activities. This preferential effect is not absolute, however, and at higher doses, atenolol inhibits $beta_2$-adrenoceptors chiefly located in the bronchial and vascular musculature.

In man, absorption of an oral dose is rapid and consistent but incomplete. Approximately 50% of an oral dose is absorbed from the gastro-intestinal tract, the remainder being excreted unchanged in the faeces.

Peak blood levels are reached between 2 to 4 hours after ingestion. Atenolol undergoes little or no metabolism by the liver and the absorbed portion is eliminated primarily by renal excretion. The elimination half-life is approximately 6 to 7 hours. When renal function is impaired, elimination is closely related by the glomerular filtration rate, significant accumulation occurs when creatinine clearance falls below 35 mL/ min.

INDICATIONS

For the treatment of hypertension, angina pectoris, acute myocardial infarction and cardiac arrhythmias.

CONTRAINDICATIONS

Atenolol should not be given to patients with sinus bradycardia, partial heart block, cardiogenic shock or overt cardiac failure.

ADVERSE REACTIONS

Most adverse effects have been mild and transient. The more frequent adverse effects include decreased sexual ability, drowsiness, trouble in sleeping, unusual tiredness and weakness.

Other less frequent adverse effects are anxiety, constipation, diarrhoea, nasal congestion, nausea, stomach discomfort, bradycardia, dizziness, bronchospasm, congestive heart failure, mental depression, reduced peripheral circulation.

Other rare side-effects are skin rash, arrythmias; back pain, chest pain, confusion, hallucinations, hepatotoxicity, leucopenia, orthostatic hypotension, thrombocytopenia, sore eyes and change in taste perception.

PRECAUTIONS

Caution is recommended in patients with a history of allergy, bronchial asthma, emphysema, congestive heart failure, diabetes mellitus, renal function impairment, hyperthyroidism or a history of mental depression. Atenolol may also aggravate peripheral arterial circulatory disorders. Beta-blockers should be used with caution in patients with COPD or bronchospastic disease. Avoid abrupt withdrawal in patients with coronary artery disease as it could result in exacerbation of angina arrythmias or myocardial infarction.

Pregnancy

Atenolol can cause foetal harm when administered to a pregnant woman. Atenolol crosses the placental barrier and appears in cord blood. Administration of atenolol, starting in second trimester of pregnancy, has been associated with the birth of infants that are small for gestational age. No studies have been performed on the use of atenolol in the first trimester and the possibility of foetal injury cannot be excluded.

If the drug is used during pregnancy, or if the patient become pregnant while taking this drug, the patient should be apprised of the potential hazard to the foetus.

Breast-feeding

Atenolol is excreted in human breast milk at a ratio 1.5 to 6.8 when compared to the concentration in plasma. Caution should be exercised when atenolol is administered to a nursing woman. Clinically significant bradycardia has been reported in breast-fed infants. Premature infants or with impaired renal function, may be more likely to develop adverse effects.

Effects on Ability to Drive and Use Machine:

Atenolol has no or negligible influence on the ability to drive and use machines. However, it should be taken into account that occasionally dizziness or fatigue may occur.

Drug Interaction

Patients already on beta-blocker must be evaluated carefully before atenolol is administered.

Catecholamine-depleting drugs eg. Reserpine may have an additive effect when given with beta-blocking agents. Calcium channel blockers may have an additive effect with beta-blockers causing bradycardia and heart block. Beta-blockers may exacerbate the rebound hypertension which can follow the withdrawal of clonidine. If the two are co-administered, the beta-blocker should be withdrawn several days before the gradual withdrawal of clonidine. While taking beta-blockers patients with a history of anaphylactic reaction to a variety of allergens may have a more severe reaction on repeated challenge, either accidental, diagnostic or therapeutic. Such patients may be unresponsive to the usual doses of adrenaline used to treat the allergic reaction.

DOSAGE AND ADMINISTRATION

Usual adult dose:

Angina Pectoris:

Initially 50 mg once a day; the dosage being increased to 100 mg once a day after more than one week if necessary and tolerated. Some patients may require up to 200 mg once a day for optimal effect.

Hypertension:

Initially 25 to 50 mg once a day either alone or added to diuretic therapy. The dosage can be increased to 50 mg to 100 mg once a day after two weeks if necessary and tolerated.

Cardiac arrhythmias

Initially controlled intravenously. Having controlled the arrhythmias with intravenous atenolol, a suitable oral maintenance dosage is 50-100 mg daily, given as a single dose.

Acute Myocardial Infarction:

In patients who tolerate the full intravenous dose, 50 mg oral atenolol should be initiated 10 minutes after the last intravenous dose followed by another 50 mg oral dose 12 hours later. Thereafter, atenolol can be given either 100 mg once daily or 50 mg twice a day for a further 6-9 days or until discharged from hospital. If bradycardia or hypotension requiring treatment or any other untoward effects occur, atenolol should be discontinued.

Elderly patients:

Geriatric patients may have increased or decreased sensitivity to the effects of the usual dose.

Patients with severe renal function:

Creatinine clearance (mL/min/1.73m²)	Maximum dose
15-35	50 mg per day
Less than 15	50 mg every second day

Usual paediatric dose:

Dosage has not been established.

OVERDOSAGE

Symptoms:

Lethargy, bradycardia, dizziness, hypotension, irregular heartbeat, difficulty in breathing, blush-coloured fingernails or palms of hands or seizures.

Treatment:

Treatment of overdose should be directed to the removal of any unabsorbed drug by induced emesis, gastric lavage or administration of activated charcoal. Atenolol can be removed from the general circulation by haemodialysis. Other treatment may include for:

Bradycardia: Atropine intravenously. If there is no response to vagal blockade, give isoproterenol cautiously. In refractory cases, a transvenous cardiac pacemaker may be indicated.

Heart block (2^{nd} and 3^{rd} degree): Isoproterenol or transvenous cardiac pacemaker.

Cardiac failure: Digitalize the patient and administer a diuretic. Glucagon has been reported to be useful.

Hypotension: Vasopressors such as dopamine or noradrenaline. Monitor blood pressure continuously.

Bronchospasm: A $beta_2$-stimulant such as isoproterenol and/ or aminophylline.

(L)250mm

(W)200mm

Hypoglycaemia: Intravenous glucose.

ROUTE OF ADMINISTRATION
Oral.

STORAGE CONDITIONS
Store below 30 °C.
Protect from light.

SHELF LIFE
Product should not be used beyond the expiry date imprinted on the product packaging.

PRESENTATION
Pharmaniaga Atenolol tablet 50 mg
In blisters of 100 and 250 tablets.

Pharmaniaga Atenolol tablet 100 mg
In blisters of 30, 100, 250 and 500 tablets.

Date of revision: 10th July 2017

PRODUCT REGISTRATION HOLDER/ MANUFACTURER:
PHARMANIAGA MANUFACTURING BERHAD
(60016-D)
11A, Jalan P/1, Kawasan Perusahaan Bangi,
43650 Bandar Baru Bangi, Selangor Darul Ehsan,
Malaysia.

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