PACKAGE INSERT

TENOL TABLET 50MG

Each tablet contains:
Atenolol 50mg

Product Description:
Round, white, flat, plain tablet with score on one side only.

Pharmacodynamics:
Atenolol is a beta-adrenoceptor blocking agent which is cardioselective but possesses neither membrane stabilising activity nor intrinsic sympathomimetic activity.
As with other β-blockers, its mode of action in the treatment of hypertension is unclear. It is probably the action of Atenolol in reducing cardiac rate and contractility which makes it effective in eliminating or reducing the symptoms of patients with angina.
Early intervention with Atenolol in acute myocardial infarction reduces infarct size and decreases morbidity and mortality. Fewer patients with a threatened infarction progress to frank infarction; the incidence of ventricular arrhythmias is decreased and marked pain relief may result in reduced need of opiate analgesics. Early mortality is decreased. Atenolol is an additional treatment to standard coronary care.

Pharmacokinetics:
Absorption of atenolol following oral dosing is consistent but incomplete (approximately 40-50%) with peak plasma concentrations occurring 2-4 hours after dosing. There is no significant hepatic metabolism of atenolol and 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 tissue poorly due to its low lipid solubility and its concentration in brain tissue is low. Plasma protein-binding is low (approximately 3%).

Indication:
Treatment of hypertension, angina pectoris, myocardial infarction and cardiac arrhythmias.

Recommended Dosage:
a) For hypertension : 100mg daily as single dose.
b) For angina pectoris : 100mg daily as single dose or divided doses.
c) For cardiac arrhythmias : 50mg to 100mg daily when cardiac arrhythmias has been controlled.
d) For myocardial infarction : 5 to 10 mg should be given immediately by slow IV injection followed by 50mg orally about 15 minutes later provided no untoward effects occur from IV dose. This should be followed by 50mg orally 12 hours after the IV dose and then 12 hours later by 100mg orally to be given once daily.

Route of Administration: Oral

Contraindications:
It is contraindicated in patients who have second and third degree heart block, uncompensated heart failure and cardiogenic shock.

Warnings and Precautions:
a) It may be used with caution in patients with chronic obstructive airways disease.
b) It should not be given to patients with congestive heart failure unless whose signs of failure have been controlled.
c) Care should be taken in prescribing with calcium-ion influx inhibitor, clonidine, digitalis glycosides and phenothiazines.
d) It should be used carefully in patients with renal function impairment, hyperthyroidism and diabetes.
e) It should never be given to patients with pheochromocytoma without concomitant α-adrenoceptor blocking therapy.
f) Great care be exercised in giving atenolol to patients undergoing anesthesia, myocardial depressant, depressant agents.

Interactions with Other Medicaments:
The effects of salbutamol and isoprenaline on the bronchi are not impaired by atenolol.
Atenolol can therefore be used in patients with obstructive airways disease provided appropriate care is taken.
Where ventricular function is impaired, β-blockers and calcium antagonists of the verapamil type should be combined only with care. Such combinations must be avoided in conduction disorders.
Care is needed when β-blockers are combined with class 1 antiarrhythmic agents, eg disopyramide. Care is also required when a change is made from clonidine to atenolol. If clonidine is given together with a β-blocker and treatment is discontinued, the β-blocker should be discontinued a few days before clonidine treatment is discontinued.
It is not advisable to discontinue a β-blocker before anaesthesia. Certain reactions during anaesthesia are altered by β-blockade. The anaesthetist must therefore be informed if a patient being treated with atenolol has to have a general anaesthetic. Vagal stimulation can be counteracted by atropine 1-2 mg IV.
In some circumstances atenolol can potentiate the hypoglycaemic effect of insulin.

Pregnancy and Lactation:
Atenolol crosses the placental barrier and appears in the cord blood. No studies have been performed on the use of Atenolol in the 1st trimester and possibility of foetal injury cannot be excluded. Atenolol has been used under close supervision for the treatment of hypertension in the 3rd trimester. Administration of Atenolol for longer periods to pregnant women in the management of mild to moderate hypertension has been associated with intrauterine growth retardation. The use of Atenolol in women who are, or may become pregnant, requires that the anticipated benefit be weighed against the possible risks, particularly in the 1st and 2nd trimesters. There is significant accumulation of Atenolol in breast milk. Caution should be exercised when Atenolol is administered to a nursing woman.

Side Effects:
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 paraesthesia.
CNS system effects include: Depression, hallucination and disturbances of sleep and vision.
Blood disorders and skin rashes may also occur. Other adverse effects reported include constipation, fluid retention and weight gain, muscle cramps and dry mouth.

Symptoms and Treatment of Overdose:
Symptoms include bradycardia, severe hypotension, heart failure and as stated in ADVERSE EFFECTS.
Treatment: (a) Emptying the stomach by aspiration and lavage.
(b) Bradycardia and severe hypotension should be treated with intravenous injection of 1 to 2mg of atropine. Followed, if necessary, by 25mcg of isoprenaline or 500mcg of orciprenaline by slow intravenous injection.
(c) Heart failure should be treated with digitalis and diuretic therapy.
(d) High doses of glucagon should be given early in severe overdosage.

Storage Conditions:
Store at or below 30°C. Protect from light.

Pack Size: Blister pack: A box of 10 x 10, 50 x 10 and 100 x 10 tablets per strip.
Pack Size (export only): A bottle of 500 tablets.

Shelf-life: 3 years.

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

Manufacturer & Product Registration Holder:
SUNWARD PHARMACEUTICAL SDN. BHD.
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