

PACKAGE INSERT

ORADAY TABLET



COMPOSITION

Each tablet contains : Atenolol 100 mg

DOSAGE FORM AVAILABLE TABLET

PRODUCT DESCRIPTION

Round, biconvex, white film-coated tablet bisected on one face and impressed BIOLAB's logo on the obverse.

ACTIONS

ORADAY (Atenolol) is a β_1 -Selective blocking agent within myocardium. It causes vascular smooth muscle. By inhibiting myocardial β -adrenergic receptors, atenolol causes the decrease in myocardial contractility and heart rate, as well as the reduction in blood pressure which lead to a reduction in myocardial oxygen consumption.

Pharmacokinetics :

Absorption : Atenolol is rapidly but incompletely absorbed from GI tract only about 50-60% of an oral dose is absorbed. In healthy adults, peak plasma concentrations of 1-2 $\mu\text{g/ml}$ are achieved after oral administration of a single 200-mg dose of Atenolol at 2-4 hours.

Distribution : In animals, Atenolol is well distributed into most tissues and fluids except brain and CSF. Only small portion of Atenolol is apparently distributed into CNS.

Approximately 5-15% of Atenolol is bound to plasma protein. Atenolol readily crosses the placenta, fetal serum concentrations of drug probably equivalent to those in maternal serum. Atenolol is also distributed into milk, the amount is believed to be too small to

OVERDOSAGE

Symptoms : Overdosage of Atenolol may be expected to produce effects that are mainly extensions of pharmacologic effects, including symptomatic bradycardia, hypotension, bronchospasm, and acute cardiac failure; hypoglycemia may also occur.

Treatment and Antidote : In acute Atenolol overdose, the stomach should be emptied immediately by gastric lavage. Supportive and symptomatic treatment should be initiated. For symptomatic bradycardia, IV Atropine sulphate may be given and for second- or third-degree AV block, IV Isoproterenol HCl or a transvenous cardiac pacemaker may be used. A vasopressor (e.g., Dobutamine, Dopamine, Epinephrine, Norepinephrine) may be given for severe hypotension ; IV Glucagon may be useful if hypotension is refractory to vasopressors. A β -adrenergic agonist (e.g., Isoproterenol), Atropine, or IV Aminophylline may be given for bronchospasm. For heart failure, a cardiac glycoside, diuretic, and oxygen should be used ; IV Glucagon also may be useful. Hypoglycemia should be treated with IV Dextrose. Hemodialysis may be useful in enhancing elimination of Atenolol in patients with severe overdosage.

CONTRAINDICATIONS

- Patients with Bronchial asthma or Bronchospasm, Hypoglycemia, Metabolic acidosis.
- During pregnancy and lactation.

PRECAUTIONS AND WARNINGS

1. Should be given with caution to patients with impaired renal function.
2. Should be used with caution in patients with inadequate cardiac function.
3. Should be used with caution in patients with bronchospastic disease.
4. Should be used with caution in patients diabetes mellitus or hyperthyroidism.

SIDE EFFECTS/ADVERSE REACTIONS

The most common side effects are nausea, vomiting, diarrhea and other GI disturbances, fatigue, dizziness, mental depression, bradycardia, hypotension, Raynaud's phenomenon, bronchospasm. Blood disorders, skin rashes may also occur.

DRUG INTERACTIONS

Concomitant administration of Atenolol with β -adrenergic agonists may increase the incidence of hypotension and bradycardia as compared with Atenolol alone, because of β -adrenergic catecholamine-depleting activity. Atenolol may also interact with other drugs that affect the cardiovascular system.