

DYNORMIN TABLET 50MG

DESCRIPTION:

TABLET

Colour : White
Shape : Round, Biconvex and Scored
Coating : Film-coated

EACH TABLET CONTAINS: Atenolol..... 50 mg

PHARMACODYNAMICS:

Atenolol is a β -adrenoceptor blocking agent which is cardioselective (i.e. acts preferentially on β -adrenergic receptors in the heart). It is without intrinsic sympathomimetic and membrane stabilising activities. It crosses the blood brain barrier only to a negligible extent. Atenolol is effective for at least 24 hours after a single oral dose.

PHARMACOKINETICS:

Atenolol appears to be incompletely absorbed from the gastrointestinal tract and is not significantly metabolised. It is excreted in the urine and its biological half-life is longer than would be anticipated from its plasma half-life of about 6 to 7 hours. Atenolol diffuses across the placenta and is excreted in the breast milk. Only small amounts are reported to cross the blood-brain-barrier, and it is only about 5% bound to plasma proteins.

INDICATION:

Control of hypertension. Management of angina pectoris and cardiac dysrhythmias. Prophylaxis of myocardial infarction.

RECOMMENDED DOSE:

Hypertension: Most patients reported to 50 - 100 mg daily given orally as a single dose. The effect will be fully established after one to two week.

Angina: Most patients with angina pectoris will respond to 100 mg daily given orally as a single or divided dose. It is unlikely that additional benefit will be gained by increasing the dose.

Dysrhythmias: Having controlled the dysrhythmias with intravenous administration of Atenolol, a suitable oral maintenance dosage is 50 - 100 mg daily, given as a single dose.

Myocardial Infarction: Treatment should be given within 12 hours of the onset of chest pain: 5 to 10 mg should be given by I.V. injection and followed after 15 minutes with 50 mg by mouth, provided no adverse effect result. A further 50 mg may be given after 12 hours and subsequent dosage maintained, after a further 12 hours, with 100 mg daily. The dosage should be reduced in renal failure.

For patients with severe renal function impairment, the following maximum doses are recommended.

CrCl (ml/min/1.73m ²)	Maximum Dose
15 - 35	50 mg/day
< 15	50 mg on alternate days

CONTRAINDICATIONS:

It should not be used in the presence of second or third degree heart block. It should not be used in patients with cardiogenic shock.

Risk and benefit should be considered when it is given to the patients with: asthma/bronchospasm, history of obstructive airway disease, metabolic acidosis, sinus bradycardia, partial heart block, cardiogenic shock or overt cardiac failure, diabetes mellitus.

WARNING AND PRECAUTIONS:

Special care should be taken with patients whose cardiac reserve is poor. β -adrenoceptor blocking drugs should be avoided in overt heart failure. However, they may be used in patients whose signs of failure have been controlled. One of the pharmacological actions of Atenolol is to reduce heart rate. In the rare instances when symptoms may be attributable to the slow heart rate, the dose may be reduced. Atenolol modifies the tachycardia of hypoglycaemia. Atenolol may be used with caution in patients with chronic obstructive airways disease. However, some increase in airways resistance may occur occasionally in asthmatic patients. This can usually be reversed by commonly used dosage of bronchodilators such as Salbutamol or Isoprenaline. In patients suffering from ischaemic heart disease, as with other β -blocking agents, treatment should not be discontinued abruptly.

Care should be taken in prescribing a β -adrenoceptor blocking drug with Class 1 antidysrhythmic agents such as disopyramide. β -adrenoceptor blocking drugs should be used with caution in combination with Verapamil in patients with impaired ventricular function. The combination should not be given to patients with conduction abnormalities. Caution should be exercised when transferring patients from clonidine to β -adrenoceptor blocking drugs. If β -adrenoceptor blocking drugs and clonidine are given concurrently, clonidine should not be discontinued until several days after withdrawal of the β -adrenoceptor blocking drug. Since Atenolol is excreted via the kidneys, dosage should be adjusted in cases of severe impairment of renal function. Risk-benefit should be considered when give to pregnant mother or during breast feeding.

INTERACTIONS WITH OTHER MEDICAMENTS:

Atenolol may enhance the effects of hypoglycaemic agents (eg. Insulin) in the patients with diabetes mellitus. Great care should be exercised in giving Atenolol to patients undergoing anaesthesia, and myocardial depressants, eg. halothane, cyclopropane or ether should be avoided.

The effects of other myocardial depressant agents including antiarrhythmics, eg. Quinidine, Procainamide or Lignocaine, Phenytoin and drugs which interfere with calcium transport, eg. Verapamil, may be enhanced by Atenolol.

The effects of Atenolol are diminished by β -adrenoceptor stimulating agents eg. Isoprenaline; the hypotensive effects of alcohol may be dangerously reversed and the peripheral vasoconstrictor effects enhanced by α -adrenoceptor stimulating agents, eg. Noradrenaline or those with mixed α - and β -adrenoceptor-stimulating properties, eg. adrenaline; bradycardia may also occur. The effects of Atenolol may be enhanced by adrenergic neurone blocking agents, eg. Guanethidine or bethanidine or catecholamine-depleting agents, eg. reserpine and the hypertensive effects by diuretics.

Atenolol may enhance some of the cardiac effects of digitalis and diminish others. It has been suggested that clonidine withdrawal symptoms may be exacerbated in patients who are concurrently taking a β -blocker.

Significant hypertension may occur up to 14 days following discontinuation of MAO inhibitor (eg. Furazolidone, Procarbazine and Selegiline). So concurrent use with Atenolol is not recommended.

PREGNANCY AND LACTATION:

Atenolol crosses the placenta. The safety of Atenolol if given in early pregnancy has not been established and its use should therefore be avoided. β -blockers reduce placental perfusion, which may result in intrauterine foetal death, immature and premature deliveries. In addition, adverse effects (especially hypoglycaemia and bradycardia) may occur in foetus and neonate in the postnatal period.

Administration of Atenolol in pregnancy may be associated with reduced foetal growth, which is greatest when started in early pregnancy, such as in the second trimester and is related to the duration of treatment. The risk of adverse effects to the foetus or neonate is greater in severely hypertensive pregnancies.

However, Atenolol has been used effectively under close supervision for the treatment of hypertension in the third trimester.

Atenolol is excreted in breast milk. Breast-feeding can be undertaken but infants should be monitored for bradycardia, respiratory depression, hypotension and hypoglycaemia.

SIDE EFFECTS:

Skin rashes, dry eyes, coldness of the extremities, muscular fatigue and in isolated cases, bradycardia. Sleep disturbances rarely occur. The incidence of side-effect is few and in most cases, the symptoms will disappear when treatment is ceased. Discontinue the drug if any side-effect is not explicable and consult the physician.

SYMPTOMS AND TREATMENT OF OVERDOSE:

Symptoms of overdose: Bradycardia; severe dizziness or fainting; hypertension; irregular heartbeat; difficulty breathing; bluish-coloured fingernails or palms of hands or seizures.

Usually overdose of Atenolol can be treated by symptomatic and supportive treatment eg. gastric lavage and administration of Activated Charcoal.

Special treatment may include:-

Diazepam or Lorazepam: May be used intravenously to treat associated seizures.

Atropine: May be administered for severe bradycardia in the presence of hypertension. Excessive bradycardia can be countered with Atropine 1 - 2 mg intravenously. If necessary, this may be followed by a bolus dose of glucagon 10 mg intravenously or by an intravenous infusion of glucagon 1 - 10 mg/hour depending on response. If no response to glucagon occurs or if glucagon is unavailable a β -adrenoceptor stimulant such as prenalterol 5 mg intravenously, followed if necessary by an intravenous infusion of 5 mg/hour or dobutamine 2.5 to 10 mcg/kg/min by intravenous infusion may be given. There is a possibility of hypotension occurring following the use of β -adrenoceptor agonists but this will be reduced by the use of the more selective agents, eg. prenalterol and dobutamine.

Transvenous pacing: May be necessary for heart block.

Other therapy: May include Furosemide or digitalis glucoside for pulmonary edema or cardiac failure; or a β_2 agonist such as Isoproterenol and/or a Theophylline derivative for bronchospasm.

PACKING/PACK SIZE(S):

Blister pack of 10x10's & 50x10's.

JAUHI UBAT DARIPADA KANAK-KANAK

KEEP OUT OF REACH OF CHILDREN

MANUFACTURER/PRODUCT REGISTRATION HOLDER:

DYNAPHARM (M) SDN. BHD. 198001011897 (65683-V)

2497, Mk. 1, Lorong Perusahaan Baru 5,

Kawasan Perusahaan Perai 3,

13600 Perai, Pulau Pinang, MALAYSIA

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