Important Information. Please read carefully.

NORMATEN®

Atenolol

50mg / 100mg Tablets

Atenolol 50 / 100mg

Composition

Normaten Tablets 50mg : Each tablet contains Atenolol 50mg.
Normaten Tablets 100mg : Each tablet contains Atenolol 100mg.

Pharmacodynamics

Atenolol is a hydrophilic $ß_1$-adrenoceptor blocking drug with general properties similar to those of propranolol. It reduces cardiac activity by diminishing or preventing sympathetic ß-adrenoceptor stimulation. It reduces the rate and force of contraction of the heart and decreases the rate of conduction of impulses through the conducting system. Its principal effect is to reduce the response of the heart to stress and exercise and it reduces blood pressure in patients with hypertension. Atenolol is classified as cardioselective and is reported to lack intrinsic sympathomimetic activity and membrane stabilising properties.

Pharmacokinetics

Atenolol is 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 - 7 hours. Atenolol diffuses across the placenta and is excreted in breast milk. Only small amounts are reported to cross the blood brain barrier, and it is only about 5% bound to plasma protein.

Indications

Normaten is indicated for the control of hypertension and management of angina pectoris. It is also used as oral maintenance therapy for cardiac dysrhythmias after the acute attacks has been controlled by intravenous therapy and for long-term prophylaxis of myocardial infarction after recovery.

Dosage and Administration

In adult and children over 12 years :

Hypertension : 50 to 100mg daily as a single dose. The effects will be fully established after 1 to 2 weeks. A further reduction in blood pressure may be achieved by combining Atenolol with other antihypertensive agents.

Angina : 50mg twice daily or 100mg daily once. It is unlikely that the higher dose would be additionally beneficial.

Dysrhythmias : Initially controlled intravenously. Oral maintenance dosage of 50 - 100mg daily, given as a single dose.

Myocardial infarction : In suitable patients, initially controlled intravenously, followed by 50mg Normaten orally, 15 minutes after the intravenous dose, provided no adverse effects occur. This should be followed by a further 50mg orally 12 hours later, then 24 hours later by 100mg orally to be given once daily for up to 10 days. If bradycardia and/or hypotension, or other adverse effects occur, requiring treatment, Normaten should be discontinued.

The elderly : Dosage requirements may be reduced, especially in patients with impaired renal function.

Children : There is no paediatric experience with Atenolol. Atenolol is not recommended for use in children under 12 years of age.

Dosage should be adjusted in patients with severe impairment of renal function as Atenolol is excreted via kidneys.

Creatinine clearance:	Dosage:
>35ml/min/1.73 m²	no adjustment required
15 - 35ml/min/1.73 m²	50mg daily or 100mg once every two days
<15ml/min/1.73 m²	50mg on alternate days or 100mg once every four days

Contraindications

It is contraindicated in patients with bronchospasm or obstructive airways disease, metabolic acidosis, sinus bradycardia, or partial heart block (second or third degree heart block). It should not be used in patients with cardiogenic shock and in overt heart failure.

Precautions

Atenolol should not be given to patients with phaeochromocytoma without concomitant α-adrenoceptor blocking therapy. Use with caution in pregnancy, during breast feeding, in patients with inadequate cardiac function, diabetes mellitus or hyperthyroidism.

Avoid abrupt withdrawal especially in patients with coronary artery disease, since it may exacerbate angina or precipitate myocardial infarction. Reduce dose may be required in patients with renal failure.

Special care should be taken with patients whose cardiac reserve is poor. ß-adrenoreceptor blockers 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 Normaten is to reduce heart rate. In rare instances when symptoms may be attributable to the slow heart rate, the dose may be reduced. Normaten modifies the tachycardia of hypoglycaemia.

Although cardioselective ($ß_1$) ß-blockers may have less effect on lung function than non-selective ß-blockers, as with all ß-blockers, these should be avoided in patients with reversible obstructive airways disease, unless there are compelling clinical reasons for their use. Where such reason exist, Normaten may be used with caution. Occasionally, some increase in airway resistance may occur in asthmatic patients, however, and this may usually be reversed by commonly used of bronchodilators such as salbutamol or isoprenaline.

In patients suffering from ischaemic heart disease, as with other ß-blocking agents, treatment should not be discontinued abruptly.

Anaesthesia : Care should be taken when using anaesthetic agents with Normaten. The anaesthetist should be informed and the choice of anaesthetic should be the agent with as little negative inotropic activity as possible.

See also section under Drug Interactions below.

Effects on Ability to Drive and Use Machine

Use is unlikely to result in any impairment of the ability of patients to drive or operate machinery. However, it should be taken into account that occasionally dizziness or fatigue may occur.

Drug Interactions

Normaten may enhance the effects of other myocardial depressant including anti-arrhythmics such as quinidine, procainamide, lignocaine, phenytoin and verapamil. The effects of Atenolol may be diminished by isoprenaline and may be enhanced by guanethidine, bethanidine, reserpine, and diuretics. Its peripheral vasoconstrictor effects may be enhanced by noradrenaline and adrenaline.

Caution should be exercised when transferring patients from clonidine to ß-adrenoreceptor blocking drugs. If ß-adrenoreceptor blocking drugs and clonidine are given concurrently, clonidine should not be discontinued until several days after the withdrawal of the ß-adrenoreceptor blocking drugs (see also prescribing information on clonidine)

Care should be exercised in prescribing a ß-adrenoreceptor blocking drug with Class 1 antidysrhythmic agents such as disopyramide.

ß-adrenoreceptor 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. Neither drug should be administered intravenously with 48 hours of discontinuing the other.

Incompatibilities

None known.

Side Effects

Atenolol shares the toxic potentials of ß-adrenergic blocking agents. In therapeutic dosage, it is well tolerated and has low incidence of adverse effects.

Cardiovascular Effects : Potentially serious adverse cardiovascular effects of atenolol include bradycardia; profound hypotension; second of third-degree atrioventricular (AV) block; and precipitation of severe congestive heart failure (CHF), which is likely to occur in patients with pre-existing left ventricular dysfunction. Other adverse cardiovascular effects include coldness of the extremities and postural hypotension.

Central Nervous System Effects : Dizziness, fatigue, and mental depression are the most common CNS effects of atenolol. Less common effects are lethargy, drowsiness, unusual dreams, light-headedness and vertigo. Other effects that may occur include visual disturbances, hallucinations, disorientation, short-term memory impairment, emotional lability, catatonia and impaired performance on neuropsychometric tests.

Gastrointestinal Effects : Adverse GI reactions include diarrhoea, nausea and vomiting.

Other Adverse Effects : The possibility of other adverse effects associated with other ß-adrenergic blocking agents that may occur include haematologic reactions (eg. agranulocytosis, nonthrombocytopenic or thrombocytopenic purpura); allergic reactions characterised by fever, sore throat laryngospasm, and respiratory distress; reversible alopecia; Peyronie's disease; Raynaud's phenomenon; erythematous rash; and impotence.

Overdosage and Treatment

In the event of severe overdosage, hospital admission is strongly advised. Symptoms of overdosage may include severe reactions of the side effects. If the overdosage is recent, stomach should be emptied by gastric lavage. Severe bradycardia and hypotension may response to atropine 1 - 2mg intravenously. Where response is inadequate, a bolus dose of 5 - 10mg glucagon may be given intravenously, followed if necessary by an I.V. infusion of glucagon 1 - 5 mg/hour depending to response. The rate of infusion should be reduced as the patient improves. Dobutamine or isoprenaline have also been used in the management of hypotension. I.V. aminophylline, or inhaled or I.V. salbutamol, may be of benefit where bronchospasm occurs. Other supportive and symptomatic treatment should be given.

Shelf-life

The expiry date is indicated on the packaging.

Presentation

Normaten Tablets 50mg : White, round, normal convex, embossed heart shape logo on one side, film-coated tablets, 7.9 mm in diameter in 28's blister film-coated tablets of 14's.

Normaten Tablets 100mg : Orange, round, normal convex film-coated tablet with heart shape logo embossed on one side, 10.0 mm in diameter in 28's blister film-coated tablets of 7's.

Storage

Protect from light and moisture. Store below 30°C.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

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Manufacturer and Product Registration Holder
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