# Atonium® Tablets

Atenolol

## DESCRIPTION

Atonium® is a beta $_1$ -selective (cardioselective) beta-adrenergic receptor blocking agent without membrane stabilizing or intrinsic sympathomimetic (partial agonist) activities. However, at higher doses, Atonium® inhibits beta $_2$ -adrenoreceptors, chiefly located in the bronchial and vascular musculature.

## COMPOSITION

Atonium® tablets is available as white round scored tablets.
Each tablet contains :
Active ingredient : Atenolol 50 mg or 100 mg.
Excipients : Corn starch, Heavy Magnesium carbonate, Sodium lauryl sulfate, Gelatin, Talc and Magnesium stearate.

## INDICATIONS

Hypertension : Atonium® is indicated in the management of hypertension. It may be used alone or concomitantly with other antihypertensive agents, particularly with a thiazide-type diuretic.

Angina Pectoris due to Coronary Atherosclerosis: Atonium® is indicated for the long-term management of patients with angina pectoris.

Acute Myocardial Infarction: Atonium® is indicated in the management of hemodynamically stable patients with definite or suspected acute myocardial infarction to reduce cardiovascular mortality.

## CONTRAINDICATIONS

Atonium® should not be used in patients with known hypersensitivity to substance, in sinus bradycardia, heart block greater than first degree, cardiogenic shock, overt cardiac failure, metabolic acidosis, severe peripheral arterial circulatory disturbances, and untreated phaeochromocytoma.

## WARNINGS

*Controlled Cardiac Failure* : In patients who have congestive heart failure controlled by digitalis and/or diuretics, Atonium® should be administered cautiously. Both digitalis and atenolol slow atrioventricular conduction.

*In Patients Without a History of Cardiac Failure* : Continued depression of the myocardium with beta-blocking agents over a period of time can, in some cases, lead to cardiac failure. Patients should be fully digitalized and/or be given a diuretic. If cardiac failure continues Atonium® should be withdrawn.

*Cessation of Therapy with Atonium®* : If withdrawal of Atonium® therapy is planned, it should be achieved gradually and patients should be carefully observed for angina and/or myocardial infarction and ventricular arrhythmias, and advised to limit physical activity to a minimum.

*Bronchospastic Diseases* : Patients with bronchospastic disease should in general, not receive beta-blockers, unless necessary. The lowest possible dose of Atonium® should be used and a beta $_2$ stimulating agent (bronchodilator) should be made available. If dosage must be increased, dose should be divided in order to achieve lower peak blood levels.

*Concomitant Use of Calcium Channel Blockers* : Bradycardia and heart block can occur in patients with pre-existing conduction abnormalities or left ventricular dysfunction.

*Anesthesia and Major Surgery* : It is not advisable to withdraw beta-adrenoreceptor blocking drugs prior to surgery. However, care should be taken when using anesthetic agents such as those which may depress the myocardium.

*Diabetes and Hypoglycemia* : Atonium® should be used with caution in diabetics. Beta-blockers may mask tachycardia occurring with hypoglycemia, but not dizziness and sweating. At recommended doses Atonium® does not potentiate insulin-induced hypoglycemia and, unlike non-selective beta-blockers, does not delay recovery of blood glucose to normal levels.

*Thyrotoxicosis* : Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. Abrupt withdrawal of beta-blockade might precipitate a thyroid storm; therefore, patients suspected of developing thyrotoxicosis from whom Atonium® therapy is to be withdrawn should be monitored closely.

*Pregnancy and Fetal Injury* : Administration of atenolol, starting in the 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 fetal injury cannot be excluded.

## PRECAUTIONS

*General* : Atonium® may aggravate peripheral arterial circulatory disorders.

*Impaired Renal Function* : The drug should be used with caution in patients with impaired renal function.

*Drug Interactions* : Catecholamine-depleting drugs (e.g., reserpine) and calcium channel blockers may have an additive effect when given with beta-blocking agents. Beta-blockers may exacerbate the rebound hypertension which can follow the withdrawal of clonidine. While taking beta-blockers, patients may be unresponsive to the usual doses of epinephrine used to treat the allergic reactions or other problems.

*Nursing Mothers* : Caution should be exercised. Premature infants, or infants with impaired renal function, may develop adverse effects, such as bradycardia.
*Pediatric Use* : Safety and effectiveness in pediatric patients are not established yet.

## EFFECT ON ABILITY TO DRIVE OR OPERATE MACHINERY

Use is unlikely to result in any impairment in the ability of patients to drive or operate machinery. However, occasional dizziness and fatigue may occur.

## ADVERSE REACTIONS

Most adverse effects have been mild and transient. The following have been reported :

Cardiovascular : bradycardia, block, heart failure deterioration, postural hypotension, syncope, cold extremities, intermittent claudication, Raynaud's phenomenon.

CNS : confusion, dizziness, headache, mood changes, nightmares, psychoses and hallucinations, fatigue, sleep disturbances of the type noted with other beta-blockers.

Gastrointestinal : dry mouth, gastrointestinal disturbances.

Haematological : purpura, thrombocytopenia.

Integumentary : reversible alopecia, dry eyes, psoriasiform skin reactions, skin rashes.

Respiratory : bronchospasm in patients with asthma or a history of asthma.

Others : elevated liver enzymes and/or bilirubin, impotence, paraesthesia, visual disturbances, Peyronie's disease, antinuclear antibodies (ANA) and lupus syndrome.

## POTENTIAL ADVERSE EFFECTS

In addition, a variety of adverse effects have been reported with other beta-adrenergic blocking agents, and may be considered potential adverse effects of Atonium®. Agranulocytosis, allergy, central nervous system (reversible depression, short-term memory loss), gastrointestinal (mesenteric arterial thrombosis, ischemic colitis).

## OVERDOSAGE

Overdosage with Atenolol has been reported with patients surviving acute doses as high as 5 g. One death was reported after 10 g acute ingestion.

The predominant symptoms reported are lethargy, disorder of respiratory drive, wheezing, sinus pause and bradycardia. Additionally, congestive heart failure, hypotension, bronchospasm and/or hypoglycemia might also be expected.

Treatment of overdose should be symptomatic, in addition to the removal of any unabsorbed drug by induced emesis, gastric lavage, or administration of activated charcoal. Atonium® can be removed from the general circulation by hemodialysis.

## DOSAGE AND ADMINISTRATION

Hypertension : The initial dose of Atonium® is 50-100 mg given as one tablet a day. Combining with thiazides, hydralazine, prazosin, and methyldopa is possible.

Angina Pectoris : The initial dose of Atonium® is 50-100 mg given as one tablet a day. Some patients may require a dosage of 200 mg once a day for optimal effect.

Acute Myocardial Infarction : Atonium® Tablets should be given at 50 mg twice daily or 100 mg once a day for at least seven days, continued for one to three years.

Elderly Patients or Patients with Renal Impairment : Dosage should be adjusted in cases of severe impairment of renal function and in elderly. No accumulation occurs until creatinine clearance falls below 35 ml/min/1.73 m $^2$ . The following maximum dosages are recommended for elderly, and in renal impairment :

| Creatinine Clearance (ml/min/1.73m$^2$) | Atenolol Elimination Half-life (h) | Maximum Dosage |
|---|---|---|
| 15-35 | 16-27 | 50 mg daily |
| <15 | >27 | 25 mg daily |

Patients on hemodialysis should be given 25 mg or 50 mg after each dialysis; this should be done under hospital supervision as falls in blood pressure can occur.

## PRESENTATION

Tablet 50 mg - blister pack of 30's
Tablet 100 mg - blister pack of 30's

## STORAGE CONDITIONS

Store in a dry place below 30$^{o}$C, protected from light.
Do not refrigerate.

**Do not use after expiry date.**

**This is a medicament**

-A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

**Keep medicament out of reach of children.**

Manufactured in Zouk Mosbeh Lebanon by
ALGORITHM S.A.L.


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