Blokium 100 mg Comprimidos/Tablets/Comprimés

Atenolol

Composition per tablet
Atenolol (INN) ..... 100 mg

Excipients: sodium starch glycolate, microcrystalline cellulose, magnesium stearate and povidone.

Pharmaceutical form and contents of container
Tablets for oral use. Packages of 15 and 30 tablets.

Pharmacological properties
Atenolol (the active ingredient of Blokium) is a beta adrenoreceptor blocker acting primarily on the cardiac beta-1 receptors. The product has no intrinsic sympathomimetic activity or membrane stabilising properties. Atenolol does not go through the hematoencephalic barrier.
Because of its simple dosage pattern and prompt response, Blokium constitutes an effective medication, above all in antihypertensive therapy, and is well tolerated by the patient. Blokium can be administered concomitantly with diuretics and other hypotensive agents.

Pharmacokinetic properties
Absorption of atenolol following oral dosing is consistent but incomplete (approximately 40-50%) with peak plasma concentrations occurring 2-4 hours after dosing. The atenolol blood levels are consistent and subject to little variability. There is no significant hepatic metabolism of atenolol and more than 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 tissues poorly due to its low lipid solubility and its concentration in brain tissue is low. Plasma protein binding is low (approximately 3%).

Therapeutic indications
Treatment of:
- Essential arterial hypertension.
- Angina pectoris.
- Cardiac arrhythmias.
- Acute myocardial infarction.

Contraindications
Atenolol is contra-indicated in patients with:
- Known hypersensitivity to atenolol or to any of its excipients, or to any medication from the same family (beta blockers).
- Uncontrolled heart failure, severe bradycardia, sick sinus syndrome, second or third degree heart block.
- Hypotension, severe peripheral artery circulatory disorders or cardiogenic shock.
- Untreated phaeochromocytoma or metabolic acidosis.

Precautions for use
- Take special care if you have health problems such as asthma or respiratory difficulties. Tell your doctor if you have diabetes, depression, circulatory disorders, heart, kidney, liver or thyroid problems or if you have been diagnosed with a type of coronary chest pain called Prinzmetal's angina.
- If you have had an allergic reaction to something before, such as an insect bite or sting, you should exercise caution when taking Blokium 100 mg Tablets.
- You may notice that your pulse is slower while you take these tablets. This is normal, but tell your doctor if you are concerned.
- If you are diabetic, Blokium 100 mg Tablets may mask low blood-sugar levels (hypoglycaemia) by lowering normal response, which is an increase in pulse (heart rate). It can also mask signs of hyperthyroidism or thyrotoxicosis.
- If you are admitted to hospital, tell the healthcare personnel, and especially the anesthesiologist that you are being treated with Blokium 100 mg Tablets as certain medicines used in anesthesia may be incompatible with Blokium.
- Only stop taking your tablets if your doctor tells you to and, in this case, only do so gradually.
- If you are a sportsman or sportswoman remember that this medication contains a component that may give a positive doping test result.

Warnings
Pregnancy and lactation
Atenolol crosses the placental barrier. No studies have been performed on the use of atenolol in the first trimester and the possibility of foetal injury cannot be excluded. Atenolol has been used under close supervision for the treatment of hypertension in the third trimester. Administration of atenolol to pregnant women in the management of mild to moderate hypertension has been associated with intra-uterine 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 first and second trimesters, since beta-blockers, in general, have been associated with a decrease in placental perfusion which may result in intra-uterine deaths, immature and premature deliveries.
There is significant accumulation of atenolol in breast milk.

Use in children
No experience is available on pediatric use and consequently should not be used in children.

Effects on ability to drive and use machines
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.

Interactions with other medicinal products and other forms of interaction .
- Clonidine: beta blockers may exacerbate rebound hypertension secondary to the withdrawal of clonidine.
- Calcium channel blockers (verapamil, diltiazem): severe hypotension, bradycardia and cardiac insufficiency.
- Dihydropiridines (nifedipine): increased risk of hypotension and cardiac failure.
- Class I antiarrhythmic agents (disopyramide or quinidine): decrease in cardiac output.
- Digitalis glycosides (digoxin): increased atrio-ventricular conduction time.
- Sympathomimetic agents (adrenaline): may counteract the effect of beta blockers.
- Reserpine: may enhance the effects of atenolol. .
- Analgesics (ibuprofen, indometacin): impairment of antihypertensive effects.
- Anticholinesterase agents (nasal decongestants): increased risk of bradycardia.
- The administration of other beta blockers such as celiprolol, propranolol, metoprolol, timolol, bisoprolol, carvedilol, oxprenolol or nebivolol, may increase the cardiac depression effect of atenolol.

Posology and method of administration
Hypertension: Most patients respond to a single oral dose of 100 mg. A certain number of patients can be maintained on a dose of 50 mg once a day.
The response should be evaluated after one or two weeks of continued treatment.
If the reduction in blood pressure is insufficient, atenolol can be combined with a diuretic or other antihypertensive agent.
Angina pectoris: The effective dose is usually 100 mg once a day or 50 mg twice a day. Higher doses usually do not increase efficacy.
Arrhythmias: After the initial treatment with atenolol i.v., the patient can be continued on a maintenance therapy consisting of a single daily dose of 50 or 100 mg of atenolol.
Acute myocardial infarction: Patients who have been established the intravenous beta-blocking treatment, within 12 hours after the beginning of chest pain, will be immediately administered 5-10 mg of atenolol through slow intravenous injection (1 mg/minute) followed by 50 mg of atenolol orally about 15 minutes later, if no adverse effect appears with the intravenous dose.
Later, 12 hours after the intravenous dose, 50 mg will be orally administered and, then, another 12 hours later, a 100 mg oral dose; that should be the daily dose. If bradycardia or hypotension require treatment or some other adverse effect related to atenolol occurred, the therapy must be discontinued.

Overdose
Excessive bradycardia may be counteracted with 1-2 mg of atropine i.v. If necessary, it may be followed by a bolus dose of 10 mg of i.v. glucagon which, depending on response, may be repeated or continued with an i.v. infusion of glucagon of 1- 10 mg/h. If no response is obtained with glucagon, or it is not available, a beta receptor stimulant may be used, such as prenalterol (5 mg/hour i.v.) followed by an i.v. infusion of dobutamine, if the doctor so recommends. Excessive hypotension may occur after the use of a beta-agonist. However, this may be neutralised by using more selective drugs, such as prenalterol and dobutamine.

Undesirable effects
Very Common: fatigue, sleepiness, headache, sleep disturbances, depression, difficulty breathing, peripheral vasoconstriction with coldness of the extremities and tingling sensation.
Common: bradycardia, heart block, heart failure, hypotension, hallucinations, somnolence, confusion, paraesthesia, peripheral neuritis, myopathies and visual disturbances.
Uncommon: diarrhoea, constipation, nausea, vomiting, abdominal cramps, allergic reactions, itching, reversible hair loss, impotence, loss of sexual appetite, pulmonary fibrosis and pleural effusion.
The following lab test abnormalities have been described with the use of atenolol: decrease in HDL cholesterol, decrease in platelets and increase in eosinophils in blood as well as low blood-sugar (hypoglycaemia).

Shelf life
Do not use this drug after the expiry date given on the package.

Storage Instruction
Store below 30°C

THIS IS A MEDICAMENT
- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly 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 for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of the reach of children.

Council of Arab Health Ministers - Union of Arab Pharmacists

Under medical prescription

Keep out of the reach of children

Manufacturer
Industrias Farmacéuticas Almirall, S.L.
Ctra. Nacional II, Km. 593
08740 Sant Andreu de la Barca
Barcelona (Spain)

Almirall

Almirall, S.A. 08022 Barcelona (España / Spain / Espagne)