

Bedranol®

Beta-blocker

Roche

Active substance

Propranolol HCl

Forms available

- Film-tablets, each containing 10, 40, 80 or 160 mg of Propranolol HCl
- Retard-capsules, each containing 160 mg of Propranolol HCl

Properties

Propranolol, the active substance of Bedranol, is a non-selective inhibitor of the β -adrenergic receptors which are normally stimulated by catecholamines. The non-selectivity of the drug consists in the fact that blockade occurs equally on sites β_1 and β_2 of the receptors.

Propranolol is acting mainly on the heart where β -adrenergic blockade causes a reduction in cardiac output, systolic pressure and myocardial contractility. Furthermore, the drug reduces the speed of transmission of stimuli across the heart (antl arrhythmic activity) and has an important antihypertensive activity.

Propranolol has weak stabilising properties for the membrane and is practically devoid of intrinsic sympathomimetic activity.

Pharmacokinetics

Propranolol is rapidly and almost completely absorbed from the gastro-intestinal tract with peak plasma-concentrations being reached within 2 hours following oral administration. Approximately the two thirds of the absorbed dose are metabolised in the liver at the first passage through the portal system. The drug is excreted in the urine, mainly in form of metabolites, partly free and partly conjugated. One of the these metabolites, 4-hydroxy-propranolol, has β -blocking activity similar to that of the mother molecule. The elimination half-life from plasma has been estimated about 3 hours following a single dose and about 4 hours following repeated administrations.

One Bedranol tablet of 40 mg, administered at empty stomach, provides in average a peak plasma concentration of about 40ng/ml within 3 hours. The resulting plasma elimination half-life is in average of 2 hours.

Because of the sustained release of its active substance, Bedranol Retard ensures effective blood levels during 24 hours. One daily intake of 160 mg in form of retard-capsule, instead of 4 intakes of 40 mg each in normal form, is sufficient to maintain the therapeutic effect.

Indications

- Hypertension - Angina of effort - Cardiac arrhythmias - Hypertrophic subaortic stenosis - Pheochromocytoma - Prophylaxis of migraine

Administration and dosage for adults

HYPERTENSION

Initial dose: 80 mg daily / Maintenance dose: 160 to 480 mg daily

The doctor should establish the appropriate dosage for each patient. Time necessary to reach the desired therapeutic effect may vary from a few days to a few weeks. The adjunction of a diuretic increases the hypotensive effect.

ANGINA OF EFFORT

Initial dose: 10-20 mg three or four times daily / Maintenance dose: 160 mg daily

The doctor should establish the appropriate dosage for each patient.

CARDIAC ARRHYTHMIAS (supraventricular tachycardias, tachycardias due to thyrotoxicosis)

10-30 mg three or four times daily

PHEOCHROMOCYTOMA (only if associated to an alpha-blocker)

60 mg daily during the three days preceding the operation or, in non-operable cases, 30 mg daily

PROPHYLAXIS OF MIGRAINE

Initial dose: 40 mg two to four times daily / Maintenance dose: 1 retard capsule

Unless otherwise directed by physician, for all the above-mentioned indications, the drug should be taken before meals and before going to bed.

Special dosages

Children may be treated with Bedranol under strict medical surveillance. In cases of cardiac arrhythmias, pheochromocytoma or thyrotoxicosis, the recommended dosage will be 0.25-0.5 mg/kg three to four times daily. In cases of migraine, dosage will be 20 mg two to three times daily for children less than 12 years old. For children more than 12 years old, dosage is the same as that for adults.

Use restrictions

Propranolol is contra-indicated in the following instances:

- bronchial asthma, as the blockade of β_2 -receptors may cause obstruction of the airways;
- cardiac insufficiency, bradycardia, atrio-ventricular block (unless the patients has been digitalised), for in these instances β -adrenergic stimulation is essential for the maintenance of myocardial function.

Propranolol should be given with caution in the following instances:

- insulin-treated diabetes, as the β -blockade may antagonise the regulating effect of adrenaline and hence cause excessive hypoglycemia or aggravate the symptoms of hypoglycemia;
- anaesthesia, as the effects of many narcotics are increased and prolonged by propranolol;
- pregnancy and lactation, as the drug may cross the placental barrier and be excreted in the milk of nursing mothers;
- metabolic acidosis, hyperkalemia.

It is recommended not to interrupt treatment abruptly so as to avoid rebound phenomena.

Side effects

Nausea, cold extremities, diarrhea, fatigue, bradycardia, visual troubles, bronchial constriction may occasionally occur particularly in predisposed patients. Sporadic cases of allergic reactions such as exanthema, purpura, etc. have been reported. There have also been a few reports of diminishment of libido and reversible impotence.

Interactions

The activity of propranolol is antagonised by β -adrenergic stimulants such as isoprenaline or orciprenaline.

The hypotensive effect of the drug is enhanced by diuretics, by neuron blocking agents such as guanethidine, bethanidine or reserpine, and by calcium antagonists. Verapamil increases the activity on the heart conduction.

Concomitant administration of cimetidine slows down the metabolism of propranolol with consequent accumulation of the drug in the blood. On the other hand, phenobarbital, by stimulating the microsomal enzymes in the liver, promotes "first-pass" effects and thus reduces the bioavailability of propranolol.

Taken with clonidine, propranolol may enhance the hypotensive effect of this drug.

Overdosage

In case of overdosage or exaggerated response to the drug, inject immediately 0.25 to 1 mg of atropine by i.v. followed, if necessary, by a β -adrenergic stimulant such as isoprenaline or orciprenaline.

Warning for the motorists : Since the drug may impair the reaction ability of the patient, caution is recommended when driving a car.

Keep out of the reach of children

Stability

The preparation is stable up to the expiry date shown on the commercial pack.

Presentation

- 60 and 250 tablets of 10 mg ;
- 60, 250 and 1000 tablets of 40 mg ;
- 60, 250 and 500 tablets of 80 mg ;
- 30,120 and 500 tablets of 160 mg
- packs of 14, 30 and 100 capsules of 160 mg

This is a Medicament

- Medicament is a product which affects your health, and its consumption contrary to instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instruction 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 the reach of children.

Council Of Arab Health Ministers Union of Arab Pharmacists

Information updated: June 2000