Bedranol®

Beta-blocker

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 ß-adrenergic receptors which are normally stimulated by catecholamins. The non-selectivity of the drug consists in the fact that blockade occurs equally on sites B_1 and B_2 of the receptors.
Propranolol is acting mainly on the heart where ß-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 arhythmic 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 ot 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 ß-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, provlde‌s 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 normai form, is sufficient to maintain the therapeutic effect.

Indications
- Hypertension - Angina of effort - Cardiac arhythmias - 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 ARHYTHMIAS (supraventricular tachycardias, tachycardias due to thyreotoxicosis)
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 e treated with Bedranol under strict medical surveillance. In cases of cardiac arhythmias, pheochromocytoma or thyreotoxicosis, the recommended dosage will be 0.25-0.5 mg/kg three to four times daily. !n 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 $ß_2$-receptors may cause obstruction of the airways;
- cardiac insufficiency, bradycardia, atrio-ventricular block (unless the patients has been digitalised), for in these instances ß-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 ß-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 patlents. 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 ß-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 microsomial enzymes in the liver, promotes "first-pass" effects and thus reduces the biovailability of propranolol.

Taken with clonidine, propranolol may enhance the hypotensive effect ot 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 ß-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

Manufacturer and Marketing Authorization Holder:
Lagap SA, Vezia / Switzerland

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.

Information updated: September 2013