Betagest®

Labetalol Hydrochloride BP

Description: Betagest® (Labetalol Hydrochloride) is a adrenergic receptor blocking agent contribute to a decrease in blood pressure in hypertensive patients.

Mechanism of action: Betagest® is a adrenergic receptor blocking agent that have both selective alpha1-adenergic and nonselective beta adrenergic receptor blocking actions. Both the alpha and beta blocking actions of **Betagest®** contribute to a decrease in blood pressure in hypertensive patients.

Pharmacokinetics: Labetalol Hydrochloride is completely absorbed from the gastrointestinal tract with peak plasma levels occurring 1 to 2 hours after oral administration. The plasma half-life of Labetalol following oral administration is about 6 to 8 hours. Approximately 55% to 60% of a dose appears in the urine as conjugates or unchanged Labetalol within the first 24 hours of dosing. Doses of Labetalol Hydrochloride that controlled hypertension did not affect renal function in mildly to severely hypertensive patients with normal renal function.

Composition:
Betagest® 100 tablet: Each film-coated tablet contains Labetalol Hydrochloride BP 100 mg.
Betagest® 200 tablet: Each film-coated tablet contains Labetalol Hydrochloride BP 200 mg.
Betagest® 50 mg Injection: Each 10 ml Vial Contains Labetalol Hydrochloride BP 50 mg.

Indications: Betagest® is indicated in the management of hypertension. **Betagest®** may be used alone or in combination with other antihypertensive agents, especially thiazide and loop diuretics.

Dosage & Administration:
Tablet: The recommended initial dosage of **Betagest®** is 100 mg twice daily whether used alone or added to a diuretic regimen. The usual maintenance dosage of **Betagest®** is between 200 and 400 mg twice daily.
Severe hypertensive patients: May require from 1,200 to 2,400 mg per day, with or without thiazide diuretics. Titration increments should not exceed 200 mg twice daily.
Elderly Patients: The majority of elderly patients will require between 100 and 200 mg twice daily.
IV injection: Inject 4 ml undiluted solution of **Betagest®** over 2 minutes. If necessary dose can be repeated every 10 minutes to 16 ml max. The maximal effect usually occurs within 5 minutes of each dose.
IV infusion: Add 40 ml **Betagest®** injection to 160 ml of IV solution to make final concentration 1 mg/ml. The diluted solution to be administered at a rate of 2 ml/min.

Maximum dose of **Betagest®** is 300 mg daily.

Contraindication: Labetalol Hydrochloride are contraindicated in bronchial asthma, overt cardiac failure, cardiogenic shock, sever bradycardia, other conditions associated with sever and prolonged hypertension and in patients with a history of hypersensitivity to any component of the product.

Side Effects: Most side effects are mild and transient and occur early in the course of treatment. The incidences of adverse reactions include Fatigue, Asthenia, Headache, Nausea, Vomiting, Dyspepsia, Abdominal pain, Diarrhea, Taste distortion, Dizziness, Paresthesia, Nasal stuffiness, Increased sweating, Edema, Postural hypotension, Bradycardia, Dyspnea, Rash, Vision abnormality and Vertigo.

Use in Pregnancy & Lactation: *Pregnancy:* Teratogenic studies were performed with Labetalol in rats and rabbits at oral doses up to approximately six and four times the maximum recommended human dose (MRHD), respectively. No reproducible evidence of fetal malformations was observed. Labetalol Hydrochloride given to pregnant women with hypertension did not appear to affect the usual course of labor and delivery.
Lactation: Small amounts of Labetalol (approximately 0.004% of the maternal dose) are excreted in human milk. Caution should be exercised when Labetalol tablets are administered to a nursing woman.

Warning and Precautions: Labetalol Hydrochloride should be used with caution in patients with Impaired Hepatic Function, Congestive Heart Failure, Exacerbation of Ischemic Heart Disease, Nonallergic Bronchospasm, Pheochromocytoma, Diabetes Mellitus and Hypoglycemia.

Drug Interactions: In combination with tricyclic antidepressants may cause tremor; Cimetidine has been shown to increase the bioavailability of Labetalol Hydrochloride. If Labetalol Hydrochloride is used with nitroglycerin in patients with angina pectoris, additional antihypertensive effects may occur; Care should be taken if Labetalol is used concomitantly with calcium antagonists of the verapamil type; Both digitalis glycosides and beta-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia.

Overdose: Labetalol Hydrochloride overdose causes excessive hypotension and sometimes, excessive bradycardia. If overdose with Labetalol Hydrochloride follows oral ingestion, gastric lavage or pharmacologically induced emesis (using syrup) may be useful for removal of the drug shortly after ingestion. The following additional measures should be employed if necessary:
Excessive bradycardia-administer atropine; Cardiac failure-administer digitalis glycoside and diuretic; Hypotension-administer vasopressors (norepinephrine); Bronchospasm-administer epinephrine.

Storage: Keep out of reach of children. Store in a dry place, below 25º C temperature and protected from light.

Packaging:
Betagest® 100 Tablet: Each box contains 10x3 tablets in Alu-PVDC blister pack.
Betagest® 200 Tablet: Each box contains 10x3 tablets in Alu-PVDC blister pack.
Betagest® 50 mg IV Injection: Each box contains 1 Vial of 10 ml IV injection.

Opsonin
Opsonin Pharma
Ideas for healthcare

Manufactured by
Opsonin Pharma Limited
Rupatali, Barishal, Bangladesh