

INDOLOL *tablets*

Composition:

Each tablet contains:

- Propranolol HCl 10 , 40 mg.

Properties:

Propranolol HCl is a nonselective B-adrenergic receptor blocking agent possessing no other autonomic nervous system activity. It is reported to have membrane-stabilizing properties but does not possess intrinsic sympathomimetic activity. It specifically competes with beta-adrenergic receptor stimulating agents for available receptor sites. When most of beta-receptor sites are blocked by Propranolol HCl, the chronotropic, inotropic, and vasodilator responses to beta adrenergic stimulation are decreased proportionately.

Propranolol HCl is almost completely absorbed from the gastrointestinal tract, but a portion is immediately bound by the liver. Peak effect occurs in 1 – 1 ½ hour. The biologic half-life is approximately four hours. The mechanism of the antihypertensive effect of INDOLOL is mainly based on that it causes (1) decreased cardiac output (2) Inhibition of renin release by the kidneys (3) diminution of tonic sympathetic nerve outflow from vasomotor centers in the brain.

Indications:

Propranolol HCl is used in:

- the management of hypertension, it may be used alone or in combination with other antihypertensive agents, but not indicated in the management of hypertensive emergencies.
- Long-term management of patients with Angina Pectoris.
- Management of Cardiac Arrhythmias:

- *Supraventricular arrhythmias:*

1- Paroxysmal atrial tachycardias particularly those induced by digitalis or catecholamines.

2- Persistent sinus tachycardia which is non compensatory and impairs the well-being of the patient

3- Tachycardias & arrhythmias due to thyrotoxicosis.

4- Persistent atrial extrasystole which impairs the well-being of the patient.

5- Atrial flutter & fibrillation when ventricular rate cannot be controlled by digitalis alone, or when digitalis is contraindicated.

• *Ventricular tachycardias:*

1- Ventricular tachycardias induced by catecholamines or digitalis.

2- Persistent premature ventricular extrasystoles.

• *Tachyarrhythmias of digitalis-intoxication.*

- Myocardial infarction, Propranolol HCl reduce cardiovascular mortality in patients who have survived the acute phase of myocardial infarction and are clinically stable.

- Prophylaxis of common migraine headache.

- Control of anxiety and anxiety tachycardia.

- The management of hereditary essential tremor, it causes a reduction in the tremor amplitude.

• *Useful in the management of hypertrophic subaortic stenosis and improves exercise performance.*

- It is used to control symptoms of sympathetic over activity in the management of hyperthyroidism.

- Prophylaxis of upper gastrointestinal bleeding in patients with portal hypertension.

- In cases of Pheochromocytoma Propranolol HCl may be useful as adjunctive therapy if the control of tachycardia becomes necessary before or during

surgery. [should only be started in the presence of effective alpha blockade].

Dosage:

The dosage range for Propranolol HCl is different for each indication.

*** Hypertension:**

- Initial dose is 40 mg twice daily, whether used alone or with diuretic.
- Dosage may be increased gradually until adequate blood pressure control is achieved.
- The usual maintenance dosage is 120 mg to 240 mg / day & the maximum daily dose must not exceed 640 mg /day.
- The time needed for full antihypertensive response to a given dosage is variable & may range from a few days to several weeks.

*** Angina Pectoris:**

- Dosage must be individualized. Total daily doses range from 80 mg to 320 mg in divided doses.
- Oral administration of Propranolol HCl have been shown to increase exercise tolerance and to reduce ischemic changes in the ECG.
- If treatment is to be discontinued, reduce dosage gradually over a period of several weeks.

*** Arrhythmias:**

- 10 mg to 40 mg three or four times daily, before meals & at bed time [maximum daily, dose of 240 mg must not be exceeded].

*** Post-Myocardial infarction:**

- Starting dose of 40 mg 2 or 3 times daily may be increased by the same amount at weekly intervals according to patient response.
- The recommended daily dosage is 180 mg to 240 mg per day in divided doses.

*** Migraine:**

- Dose must be individualized. The initial oral dose is 80 mg daily in divided doses. The usual effective dose range is 160 — 240 mg per day. The dosage may be increased gradually to achieve optimum migraine prophylaxis [maximum daily dose must not exceed 240 mg /day].

*** *Essential tremor:***

- A starting dose of 40 mg 2 or 3 times daily may be increased by the same amount at weekly intervals according to patient response. Optimum reduction of essential tremor is usually achieved with a dose of 120 mg/day, it may be necessary to administer 240 mg to 320 mg per day.

*** *Hypertrophic Subaortic Stenosis:***

- 20 mg to 40 mg 3 or 4 times daily, before meals & at bedtime.

*** *Pheochromocytoma:***

- [INDOLOL is to be used only in the presence of effective alpha-adrenergic blocking agent].

- Preoperative: 60 mg daily for 3 days in divided doses prior to surgery.

*** *Management of inoperable malignant cases:***

- 30 mg of Propranolol HCl to be used daily in divided doses.

*** *For Elderly Patients:***

With regard to the elderly the optimum dose should be individually determined according to clinical response.

*** *For Pediatric Patients:***

- The usual pediatric dosage range is 2 mg to 4 mg / kg / day in 2 equally divided doses.

- Doses above 16 mg per kg per day should not be used in children.

- If treatment with Propranolol HCl is to be discontinued, a gradually decreasing dose titration over a 7 to 14 day period is necessary.

Packing:

INDOLOL 10 mg and INDOLOL 40 mg : boxes containing 50 tablets (5 strips x 10 tablets).