

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	RENPRESS TABLETS (Propranolol Hydrochloride BP 40 mg)
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Pack Insert

RENPRESS TABLETS
(PROPRANOLOL TABLETS BP)

Composition:

Each tablet contains Propranolol Hydrochloride BP 40mg.

INDICATIONS:

Propranolol is used for: Hypertension, angina pectoris due to coronary atherosclerosis, cardiac arrhythmias, myocardial infarction, migraine, essential tremors, hypertrophic subaortic stenosis, and pheochromocytoma.

Dosage

Adults:

Hypertension: 40 to 80mg of propranolol hydrochloride twice daily increased as required to a usual range of 160 to 320mg daily. Some patients may require doses upto 640mg.

Angina: Initial doses of propranolol hydrochloride 40mg given 2 or 3 times daily are increased a weekly intervals as required to a usual range of 120 to 240mg daily. Some patients may require upto 320mg daily.

Myocardial Infarction: 40mg given four times daily for 2 to 3 days followed by 80mg twice daily.

Cardiac arrhythmias: 30 to 160mg daily in divided doses.

Thyrotoxicosis: 10 to 40mg three or four times a day.

Migraine Prophylaxis: 40mg two or three times a day.

Essential Tremors: 40mg two or three times a day.

Children:

Hypertension: Initial doses of 1mg per kg body weight daily in divided doses increased as required to a usual range of 2 to 4mg per kg body weight daily in divided doses.

Arrhythmias, pheochromocytoma and thyrotoxicosis: 250 to 500 µg per kg body weight three of four times daily.

Migraine: Under 12 years: 20mg two or three times daily.

Adverse effects:

Cardiovascular: Bradycardia, congestive heart failure, intensification of AV block, hypotension paresthesia of hands, thrombocytopenic purpura.

Central nervous system: Light headedness, mental depression manifested by insomnia, lassitude, weakness, fatigue hallucination.

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Gastrointestinal: Nausea, vomiting, epigastric distress, abdominal cramps, diarrhea, constipation.

Allergic: Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, respiratory distress.

Respiratory: Bronchospasm.

Hematologic: Agranulocytosis, nonthrombo-cytopenic purpura, thrombocytopenic purpura.

CONTRA-INDICATIONS:

Propranolol is contraindicated in cardiogenic shock, sinus bradycardia, bronchial asthma and congestive cardiac failure.

STORAGE:

Store in a dry place at a temperature below 30°C.

PRESENTATION:

Blister pack of 10 x 10 tablets.

Bulk pack of 1000 tablets.

STRICTLY TO BE USED UNDER THE ADVICE OF MEDICAL PRACTITIONER ONLY.

KEEP OUT OF THE REACH OF CHILDREN.

MANUFACTURED BY
RENE INDUSTRIES LIMITED
Plot 680 Kamuli, Kireka.
P. O. Box 6034
Kampala, Uganda



A Milestone to Golden Health