Brand Name : PROPAN TABLETS **Generic Name :** Propranolol Tablets BP 40 mg	2021
Module 1 Administrative Information and Product Information **1.5** Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

PROPAN TABLETS (Propranolol Tablets BP 40 mg)

2. Qualitative and Quantitative Composition:

Each film coated tablet contains: Propranolol Hydrochloride Tablets BP 40 mg

3. Pharmaceutical form:

Dark pink coloured, circular, biconvex, film coated tablet having embossed 40’ on one side and plain on other side of each tablet.

4. Clinical particulars:

4.1 Therapeutic Indications:

Propranolol, sold under the brand name **Inderal** among others, is a medication of the beta blocker class. It is used to treat high blood pressure, a number of types of irregular heart rate, thyrotoxicosis, capillary hemangiomas, performance anxiety, and essential tremors. It is used to prevent migraine headaches, and to prevent further heart problems in those with angina or previous heart attacks. It can be taken by mouth or by injection into a vein. The formulation that is taken by mouth comes in short-acting and long-acting versions. Propranolol appears in the blood after 30 minutes and has a maximum effect between 60 and 90 minutes when taken by mouth.

4.2 Posology and Method of Administration:

Propranolol, It is used to treat high blood pressure.

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The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For acute heart attack:
  - For oral dosage form (solution):
    - Adults—180 to 240 milligrams (mg) per day, given in divided doses.
    - Children—Dose is based on body weight and must be determined by your doctor.
  - For oral dosage form (tablets):
    - Adults—At first, 40 milligrams (mg) three times a day. Your doctor may increase your dose if needed.
    - Children—Use and dose must be determined by your doctor.
- For adrenal gland tumor (pheochromocytoma):
  - For oral dosage form (solution):
    - Adults—60 milligrams (mg) per day, given in divided doses for 3 days before having surgery. In patients who cannot have surgery, the usual dose is 30 mg per day, given in divided doses.
    - Children—Dose is based on body weight and must be determined by your doctor.
  - For oral dosage form (tablets):
    - Adults—60 milligrams (mg) per day, given in divided doses for 3 days before having surgery. In patients who cannot have surgery, the usual dose is 30 mg per day, given in divided doses.
    - Children—Use and dose must be determined by your doctor.
- For chest pain (angina):
  - For oral dosage form (long-acting oral capsules):
    - Adults—At first, 80 milligrams (mg) once a day. Your doctor may increase your dose if needed. The dose is usually not more than 320 mg per day.
    - Children—Use and dose must be determined by your doctor.
  - For oral dosage form (solution):
    - Adults—80 to 320 milligrams (mg) per day, given in divided doses.
    - Children—Dose is based on body weight and must be determined by your doctor.
  - For oral dosage form (tablets):
    - Adults—80 to 320 milligrams (mg) per day, given in divided doses.
    - Children—Use and dose must be determined by your doctor.
- For high blood pressure (hypertension):
  - For oral dosage form (extended-release capsules):
    - Adults—At first, 80 milligrams (mg) once a day, given at bedtime. Your doctor may increase your dose if needed. However, the dose is usually not more than 120 mg per day.
    - Children—Use and dose must be determined by your doctor.
  - For oral dosage form (long-acting oral capsules):
    - Adults—At first, 80 milligrams (mg) once a day. Your doctor may increase your dose if needed.
    - Children—Use and dose must be determined by your doctor.

- For oral dosage form (solution):
  - Adults—At first, 40 milligrams (mg) two times a day. Your doctor may increase your dose if needed.
  - Children—Dose is based on body weight and must be determined by your doctor.
- For oral dosage form (tablets):
  - Adults—At first, 40 milligrams (mg) two times a day. Your doctor may increase your dose if needed.
  - Children—Use and dose must be determined by your doctor.

- For hypertrophic subaortic stenosis (thickened heart muscle):
  - For oral dosage form (long-acting oral capsules):
    - Adults—80 to 160 milligrams (mg) once a day.
    - Children—Use and dose must be determined by your doctor.
  - For oral dosage form (solution):
    - Adults—20 to 40 milligrams (mg) three or four times a day, given before meals and at bedtime.
    - Children—Dose is based on body weight and must be determined by your doctor.
  - For oral dosage form (tablets):
    - Adults—20 to 40 milligrams (mg) three or four times a day, given before meals and at bedtime.
    - Children—Use and dose must be determined by your doctor.
- For irregular heartbeats:
  - For oral dosage form (solution):
    - Adults—10 to 30 milligrams (mg) three or four times a day, given before meals and at bedtime.
    - Children—Dose is based on body weight and must be determined by your doctor.
  - For oral dosage form (tablets):
    - Adults—10 to 30 milligrams (mg) three or four times a day, given before meals and at bedtime.
    - Children—Use and dose must be determined by your doctor.
- For migraine headaches:
  - For oral dosage form (long-acting oral capsules):
    - Adults—At first, 80 milligrams (mg) once a day. Your doctor may increase your dose if needed. The dose is usually not more than 240 mg per day.
    - Children—Use and dose must be determined by your doctor.
  - For oral dosage form (solution):
    - Adults—At first, 80 milligrams (mg) per day, given in divided doses. Your doctor may increase your dose if needed.
    - Children—Dose is based on body weight and must be determined by your doctor.
  - For oral dosage form (tablets):
    - Adults—At first, 80 milligrams (mg) per day, given in divided doses. Your doctor may increase your dose if needed.
    - Children—Use and dose must be determined by your doctor.
- For proliferating infantile hemangioma:
  - For oral dosage form (solution):

Children 5 weeks to 5 months of age—Dose is based on your child's body weight and must be determined by the doctor. The starting dose is usually 0.6 milligram (mg) per kilogram (kg) of your child's body weight 2 times a day, taken at least 9 hours apart. Give the dose during or immediately after a feeding. Do not administer the dose if the infant is vomiting or not eating. After 1 week, the doctor will increase the dose to 1.1 mg per kg of body weight two times a day. After 2 weeks, the doctor will increase the dose to 1.7 mg per kg of body weight two times a day, taken for 6 months.

- Children under 5 weeks of age—Use is not recommended.

- For tremors:
  - For oral dosage form (solution):
    - Adults—At first, 40 milligrams (mg) two times a day. Your doctor may increase your dose if needed.
    - Children—Dose is based on body weight and must be determined by your doctor.
  - For oral dosage form (tablets):
    - Adults—At first, 40 milligrams (mg) two times a day. Your doctor may increase your dose if needed.
    - Children—Use and dose must be determined by your doctor.

Method of administration : Oral.

4.3 Contraindications:

See also: Beta blocker § Contraindications

Propranolol may be contraindicated in people with:

- Reversible airway diseases, particularly asthma or chronic obstructive pulmonary disease (COPD)
- Slow heart rate (bradycardia) (<60 beats/minute)
- Sick sinus syndrome
- Atrioventricular block (second- or third-degree)
- Shock
- Severe low blood pressure
- Cocaine toxicity

4.4 Pregnancy and Lactation:

Propranolol, like other beta blockers, is classified as pregnancy category C in the United States and ADEC category C in Australia. β-blocking agents in general reduce perfusion of the placenta, which may lead to adverse outcomes for the neonate, including lung or heart complications, or premature birth. The newborn may experience additional adverse effects such as low blood sugar and a slower than normal heart rate.

Most β-blocking agents appear in the milk of lactating women. However, propranolol is highly bound to proteins in the bloodstream and is distributed into breast milk at very low levels. These low levels are not expected to pose any risk to the breastfeeding infant, and the American Academy of Pediatrics considers propranolol therapy "generally compatible with breastfeeding".

5. Pharmacological properties:

5.1 Pharmacokinetic Properties:

Propranolol is rapidly and completely absorbed, with peak plasma levels achieved about 1–3 hours after ingestion. More than 90% of the drug is found bound to plasma protein in the blood. Coadministration with food appears to enhance bioavailability. Despite complete absorption, propranolol has a variable bioavailability due to extensive first-pass metabolism. Hepatic impairment therefore increases its bioavailability. The main metabolite 4-hydroxypropranolol, with a longer half-life (5.2–7.5 hours) than the parent compound (3–4 hours), is also pharmacologically active. Most of the metabolites are excreted in the urine.

Propranolol is a highly lipophilic drug achieving high concentrations in the brain. The duration of action of a single oral dose is longer than the half-life and may be up to 12 hours, if the single dose is high enough (e.g., 80 mg). Effective plasma concentrations are between 10 and 100 mg/l Toxic levels are associated with plasma concentrations above 2000 mg/l

6. Pharmaceutical particulars:

6.1 List of Excipients:

Lactose	BP
Microcrystalline cellulose	BP
Di Basic Calcium Phosphate	BP
Maize starch	BP
Gelatin	BP
Methyl Paraben sodium	BP
Propyl paraben sodium	BP
Purified talc	BP
Magnesium stearate	BP
Sodium Starch Glycolate	BP
Colloidal silicon dioxide	BP

6.2 Incompatibilities:

None Reported

6.3 Shelf-Life:

36 months from the date of manufacture.

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6.4 Special Precautions for Storage:
Store in a cool, dry and dark place. Protect from light.

6.5 Nature and Contents of Container:
10 tablets packed in one Blister. Such 10 blister packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.

6.6 Special precautions for disposal:
None reported.

7. Registrant:

AGOG PHARMA LTD.
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The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane, India.

8. Manufacturer:

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9. Date of revision of the text :