SUMMARY OF PRODUCT CHARACTERISTICS
ZENLOL 40 (Propranolol Hydrochloride Tablets BP 40 mg)

1. NAME OF THE MEDICINAL PRODUCT

ZENLOL 40 (Propranolol Hydrochloride Tablets BP 40 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains propranolol hydrochloride BP 40 mg.

Excipients with known effect:

Contains lactose (30 mg per tablet) and methyl paraben and propyl paraben (preservatives). For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet (uncoated).

White, round, flat, bevelled-edge, uncoated tablet with a break-line on one side and plain on the other.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ZENLOL 40 is indicated for: control of hypertension; management of angina pectoris; management of cardiac arrhythmias (including supraventricular tachycardia, ventricular tachycardia); management of phaeochromocytoma (pre-operatively and with an alpha-adrenoceptor blocker); prevention of migraine headache; relief of symptoms associated with thyrotoxicosis (including thyroid storm) and anxiety; management of essential tremor. ATC code: C07AA05.

4.2 Posology and method of administration

Hypertension

Initially 80 mg twice daily; may be increased to 160–320 mg/day in divided doses as needed.

Angina pectoris

Initially 40 mg two to three times daily; may be increased to 120–240 mg/day. Maximum dose 240 mg/day.

Cardiac arrhythmias

40–160 mg/day in divided doses.

Phaeochromocytoma

60 mg/day for 3 days before surgery (with alpha-blocker); 30 mg/day if surgery not possible.

Migraine prophylaxis

80–160 mg/day in divided doses.

Anxiety

40 mg once daily; may increase to 40 mg three times daily as required.

Essential tremor

40 mg two to three times daily.

Thyrotoxicosis

40 mg four times daily until thyroid status is controlled.

Special populations

Renal impairment: Propranolol is extensively metabolised; dose adjustment not generally required but use with caution in severe renal impairment. Hepatic impairment: Use with caution; reduced doses may be required. Elderly: Use with caution; start at lower doses and titrate carefully. Paediatric population: ZENLOL 40 is not recommended in children — dose adjustment to the 40 mg tablet cannot be made for standard paediatric doses.

Method of administration

Oral. May be taken with or without food.

4.3 Contraindications

- Hypersensitivity to propranolol, any of the excipients listed in section 6.1, or other beta-blockers.
- Bronchial asthma or history of bronchospasm.
- Second and third degree atrioventricular block.
- Prinzmetal's (vasospastic) angina.
- Cardiogenic shock; uncontrolled heart failure; sick sinus syndrome.
- Severe bradycardia; severe hypotension.
- Metabolic acidosis.
- Untreated phaeochromocytoma.
- Concomitant use with monoamine oxidase inhibitors (MAOIs; risk of hypertension crisis).

4.4 Special warnings and precautions for use

Bronchoconstriction

Propranolol is a non-selective beta-blocker and may induce bronchoconstriction. It is contraindicated in patients with asthma or bronchospasm. Even in patients without such history, caution is required in COPD.

Heart failure

Propranolol should not be used in patients with uncontrolled heart failure. It may be used with caution in patients with compensated heart failure, with appropriate monitoring.

Abrupt withdrawal

Do not discontinue propranolol abruptly, especially in patients with ischaemic heart disease. A gradual dose reduction over 1–2 weeks is recommended. Abrupt cessation may precipitate angina, myocardial infarction or rebound hypertension.

Hypoglycaemia

Propranolol may mask signs and symptoms of hypoglycaemia (tachycardia) in diabetic patients on insulin or oral hypoglycaemics. Use with caution in patients with diabetes or hypoglycaemia.

Thyrotoxicosis

Propranolol may mask the clinical signs of hyperthyroidism (e.g. tachycardia). Abrupt withdrawal may precipitate a thyroid storm.

First-degree AV block

Use with caution in patients with first-degree AV block.

Peripheral arterial disease

May exacerbate symptoms of peripheral arterial disease or Raynaud's phenomenon.

Sympathomimetics

Concomitant use of sympathomimetic agents (e.g. adrenaline) may counteract the effect of beta-blockers. Parenteral administration of adrenaline in patients on beta-blockers may, in rare cases, cause vasoconstriction, hypertension and bradycardia.

Surgery/anaesthesia

Propranolol may cause hypotension and impair compensatory haemodynamic responses during surgery. Caution when using combined with general or regional anaesthesia.

Lactose and parabens

This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Contains methyl paraben (E218) and propyl paraben (E216), which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Sympathomimetics (e.g. adrenaline):

May antagonise the effect of propranolol. In rare cases, parenteral adrenaline with propranolol may cause vasoconstriction, hypertension and bradycardia.

Calcium channel blockers (verapamil, diltiazem):

Additive negative chronotropic/inotropic effects; risk of AV block, bradycardia and hypotension.

Antiarrhythmics (amiodarone, lidocaine, quinidine, flecainide):

Additive cardiac effects.

Hypoglycaemic agents:

Propranolol may mask tachycardia from hypoglycaemia; may reduce glycogenolytic response to hypoglycaemia.

Antihypertensives (diuretics, ACE inhibitors, ARBs):

Additive blood pressure-lowering effect.

NSAIDs:

May reduce antihypertensive effect.

Ergotamine:

Risk of peripheral vasoconstriction.

Warfarin:

Propranolol may increase the anticoagulant effect; monitor INR.

Alcohol:

May potentiate hypotensive effect.

MAOIs (contraindicated):

Risk of hypertensive crisis.

4.6 Fertility, pregnancy and lactation

Pregnancy

Propranolol crosses the placenta and is detected in cord blood. Beta-blockers may cause neonatal bradycardia, hypotension, respiratory depression and hypoglycaemia. ZENLOL 40 should only be used during pregnancy if the benefit to the mother clearly outweighs the risk to the foetus.

Breast-feeding

Propranolol is excreted in breast milk. The risk of adverse effects in the infant should be considered.

Fertility

No data on effects of propranolol on human fertility.

4.7 Effects on ability to drive and use machines

Propranolol may cause fatigue, dizziness or vision disturbances that could impair the ability to drive and operate machines, particularly at the start of treatment.

4.8 Undesirable effects

Common: Fatigue, cold extremities, bradycardia, paraesthesia of hands, GI disturbances (nausea, vomiting, diarrhoea). Uncommon: Dizziness, sleep disturbances, bronchospasm, heart failure, postural hypotension. Rare: Alopecia, psoriasiform reactions, exacerbation of psoriasis; thrombocytopenia; mood changes; hallucinations; dry eyes; hypoglycaemia; exacerbation of peripheral arterial disease. Very rare: Myasthenia gravis-like syndrome.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Symptoms

Excessive bradycardia, AV block, hypotension, bronchoconstriction and hypoglycaemia. In severe cases, cardiogenic shock and cardiac arrest.

Treatment

General measures — maintain patent airway, breathing and circulation. Atropine (1–2 mg IV) for bradycardia. For cardiac failure: dobutamine IV infusion. For hypoglycaemia: glucose IV. For bronchospasm: bronchodilators (e.g. salbutamol by nebulisation). For severe intoxication: consider glucagon (50–150 µg/kg IV), followed by infusion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Beta-blocking agents, non-selective. ATC code: C07AA05.

Propranolol is a non-selective competitive antagonist at both beta-1 and beta-2 adrenergic receptors. It does not have intrinsic sympathomimetic activity (ISA) and does not possess membrane-stabilising activity at therapeutic plasma concentrations. The antihypertensive action is due to a combination of reduced cardiac output and blockade of peripheral beta-2 receptors, reducing renin release. The anti-anginal effect is due to reduction of myocardial oxygen demand. The antiarrhythmic effect is due to suppression of ectopic pacemaker activity and prolongation of the effective refractory period.

5.2 Pharmacokinetic properties

Absorption: Propranolol is almost completely absorbed after oral administration but undergoes extensive first-pass hepatic metabolism; absolute oral bioavailability approximately 25–30%. Food may increase bioavailability. Peak plasma concentration approximately 1–2 hours post-dose. Distribution: Protein binding approximately 93%. Highly lipophilic; readily crosses the blood-brain barrier and placenta. Volume of distribution approximately 3–5 L/kg. Biotransformation: Extensively metabolised in the liver, primarily by CYP1A2 and CYP2D6, to 4-hydroxypropranolol (active) and other inactive metabolites. Naphthoxylacetic acid is the principal urinary metabolite. Elimination: Plasma half-life 3–6 hours. Approximately 90% excreted in urine, mainly as glucuronide conjugates. Less than 1% is excreted unchanged. In patients with hepatic cirrhosis, bioavailability is increased and half-life is prolonged.

5.3 Preclinical safety data

Non-clinical studies indicate no special hazard for humans at therapeutic doses. Propranolol is teratogenic in animal studies at high doses; neonatal effects (bradycardia, hypoglycaemia) observed at therapeutic doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose BP (30 mg per tablet; excipient with known effect), maize starch BP, microcrystalline cellulose powder BP, povidone K-30 BP, methyl paraben (E218) BP (excipient with known effect), propyl paraben (E216) BP (excipient with known effect), purified water BP (manufacturing solvent), purified talc BP, magnesium stearate BP, Aerosil (colloidal silicon dioxide) BP, sodium starch glycolate BP.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

6.5 Nature and contents of container

10 tablets packed in one ALU-PVC blister; 10 such blisters packed in a carton with package insert. Pack size: 100 tablets.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

ZAIN PHARMA LTD.

Plot No. 209/13741, Colchester Park,

Go-Down No. 1, 2, 3, Off Mombasa Road,

Behind Nice and Lovely House,

P.O. Box: 100167-00101, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2026/CTD12708/27521

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

10.03.2026

10. DATE OF REVISION OF THE TEXT

10.03.2026