SCHEDULING STATUS: S3
PROPRIETARY NAME AND DOSAGE FORM:

INDOBLOK 10 (Tablets)
INDOBLOK 40 (Tablets)

COMPOSITION:
Each **INDOBLOK 10** tablet contains propranolol hydrochloride 10 mg.
Contains sugar: (Lactose 82,5 mg)
Each **INDOBLOK 40** tablet contains propranolol hydrochloride 40 mg.
Contains sugar: (Lactose 149,7 mg)
Other ingredients: Magnesium stearate, carmoisine, polyvinylpyrrolidone.
CATEGORY AND CLASS:
A5.2 Adrenolytics (Sympatholytics)
PHARMACOLOGICAL ACTION:
INDOBLOK is a non-selective beta-adrenergic blocking agent that reduces cardiac activity by diminishing or preventing beta-adrenergic stimulation. It reduces the rate of contraction, cardiac output and prolongs A-V conduction time. In response to the inhibition of the beta-adrenergic-receptors, the cardiac oxygen requirement diminishes. The blood pressure in hypertensive patients is also reduced.
INDICATIONS:

- Cardiac arrhythmias, especially supraventricular arrhythmias
- Treatment of hypertension
- Thyrotoxicosis
- Phaeochromocytoma
- Treatment of angina pectoris
- Control of anxiety – induced tachycardia and tremor.

CONTRAINDICATIONS:
INDOBLOK is contraindicated in patients with any of the following:

- Bronchial asthma or bronchospasm
- Metabolic acidosis (e.g. in diabetes)
- Atrioventricular block
- Marked bradycardia (less than 50 beats per minute)
- Heart failure refractory to digitalis
- Uraemia
- Pregnancy and lactation
- Hypoglycaemia
- Raynaud's phenomenon.
- Patients suffering from peripheral valve diseases.

Surgery:
In the pre-operative period it is generally unwise to reduce the dosage to which the patient is accustomed, as there may be danger of aggravation of angina pectoris or hypertension.
A patient's normal tachycardic response to hypoglycaemia or blood loss may be obscured during or after surgery. Particular caution should be taken in this regard.
WARNINGS AND SPECIAL PRECAUTIONS:

- Bronchospasm may occur, particularly in susceptible individuals.
- Pregnancy: Administration to pregnant mothers shortly before giving birth or during labour may result in the newborn infants being born hypotonic, collapsed and hypoglycaemic.
- Congestive heart failure: **INDOBLOK** should only be administered when the patient is fully digitalised and with great caution. This combination can be considered, despite the potentiation of negative chronotropic effect of the two medicines. Careful control of dosages and of the individual patient's response (notably pulse rate) is essential in this situation.
- Adverse reactions are more common in patients with renal decompensation.
- In diabetes mellitus **INDOBLOK** may reduce blood-sugar levels and may enhance the effects of hypoglycaemic agents.
- Particular caution should be exercised with patients suffering from any of the following conditions: Bronchitis, chronic respiratory diseases and second and third degree heart block.
- Great care should be exercised in giving **INDOBLOK** to patients undergoing anaesthesia and myocardial depressants, such as chloroform or ether, must be avoided.
- **INDOBLOK** may mask the symptoms of hyperthyroidism.

- **INDOBLOK** should never be given to patients with phaeochromocytoma without concomitant alpha-adrenergic blocking therapy.
- **Contains lactose:** Patients with the rare hereditary conditions of galactose intolerance e.g. galactosemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take **INDOBLOK**. Lactose may also have an effect on the glycaemic control of patients with diabetes mellitus.

Effects on ability to drive and use machines:
INDOBLOK can cause sleepiness or dizziness. This could lead to impaired concentration and safety when driving or operating machinery. Caution is advised.

INTERACTIONS:
It can be dangerous to administer **INDOBLOK** concomitantly with the following medicines:
Hypoglycaemic agents, phenothiazines and various anti-arrhythmic agents.
Myocardial depressant agents:
The effects of other myocardial depressant agents such as quinidine, procainamide and lignocaine may be enhanced by **INDOBLOK**.
Verapamil:
INDOBLOK should not be used with verapamil and neither compound should be administered within several days of discontinuing the other.
Calcium antagonists:
INDOBLOK should be used with caution when given together with other calcium antagonists.
Clonidine:
Caution should be used when transferring a patient from clonidine onto a beta-blocker, as this may result in a hypertensive crisis.
If **INDOBLOK** and clonidine are given concurrently, the clonidine should not be discontinued until several days after the withdrawal of **INDOBLOK** as severe rebound hypertension may occur.
Beta and alpha-adrenergic stimulating agents:
The effects of **INDOBLOK** are diminished by beta-adrenergic stimulating agents; the hypotensive effects of **INDOBLOK** may be dangerously reversed and the peripheral vasoconstrictor effects enhanced by alpha-adrenergic stimulating agents such as noradrenaline or those mixed with alpha- and beta-adrenergic stimulating properties such as adrenaline.
Adrenergic neurone blocking agents:
The effects of **INDOBLOK** may be enhanced by adrenergic neurone blocking agents such as guanethidine, bethanidine or reserpine and the hypotensive effects by diuretics.
Digitalis:
INDOBLOK may enhance some of the cardiac effects of digitalis and diminish others.

HUMAN REPRODUCTION:
INDOBLOK is contraindicated during pregnancy and lactation.
INDOBLOK is distributed into breast milk (see '**WARNINGS AND SPECIAL PRECAUTIONS**').

DOSAGE AND DIRECTIONS FOR USE:
Tablets should preferably be taken before meals.
Dosage is largely determined by the response of the patient.
In most conditions treatment should begin with a low dose and then gradually be increased.

Adults:
The usual dose of **INDOBLOK** is 20 mg to 40 mg, three or four times a day.
Treatment of hypertension: The dose may be increased up to 320 mg daily.
In phaeochromocytoma: 60 mg daily should be given for 3 days pre-operatively.
Elderly and renal dysfunction:
The normal dose should be reduced in elderly patients, or in patients suffering from renal dysfunction, as adverse effects are more common in these patients.
Weakness or faintness:
If symptoms of weakness or faintness occur, treatment should be withdrawn temporarily and started again at a lower dose which may be increased, very slowly.
Discontinuation
Abrupt discontinuation of therapy may cause exacerbation of angina pectoris in patients suffering from ischaemic heart disease. Discontinuation of therapy should be gradual and patients should be advised to limit the extent of their physical activity during the period that the medicine is being discontinued.

SIDE EFFECTS:
The most frequent side effects of **INDOBLOK** are gastrointestinal such as: nausea, constipation, vomiting and diarrhoea.

Fatigue and dizziness may also occur.
Central nervous system effects include depression, hallucinations and disturbances of sleep and vision, vivid dreams, nightmares, paradoxical hypertension, confusion and overt psychosis.
Allergic reactions, transient hearing loss, metabolic disturbances, alopecia, myopathies, dry eyes, stomatitis and malaise may also occur.
Cardiovascular effects include bradycardia, congestive heart failure, heart block, hypotension, cold extremities and parasthesia.
Development of Raynaud's phenomenon (due to unopposed arteriolar-sympathetic activation), sexual impotence, hypoglycaemia, skeletal muscle weakness and gastrointestinal disturbances may occur.
Severe peripheral vascular disease and even peripheral gangrene may be precipitated.
Blood disorders and skin rashes may also occur.
Other side effects reported include fluid retention, mass gain, muscle cramps and dry mouth.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Excessive bradycardia, severe hypotension, bronchospasm and heart failure may be produced in certain individuals.
Patients with mild overdose should be observed for at least 4 hours, as apnoea and cardiovascular collapse may appear suddenly.
Gastric lavage should be performed within 4 hours of suspected overdose. Activated charcoal is necessary in severe overdose.
Atropine may be used to treat bradycardia. If the response is inadequate, glucagon may be given intravenously. Alternatively, dobutamine or isoprenaline may be used for the management of hypotension.
Large doses of isoprenaline may be required to counteract the beta-blockade. Transvenous cardiac pacing may be required for severe bradycardia.
Bronchospasm should be treated by the intravenous injection of aminophylline or by the inhalation or intravenous injection of a selective beta-2-stimulant.
Further treatment is symptomatic and supportive.

IDENTIFICATION:

INDOBLOK 10: Round, flat, pink scored tablets (±7,1 mm in diameter).
INDOBLOK 40: Round, flat, pink scored tablets (±8,1 mm in diameter).

PRESENTATION:

Plastic containers HDPE/PP) containing 250 or 1000 tablets.
Patient ready packs (LDPE) of 28, 50, 56 or 84 tablets.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in a cool, dry place. Protect from light and moisture.
Keep HDPE/PP containers tightly closed. Do not remove tablets from HDPE/PP containers or patient ready packs until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER(S):

INDOBLOK 10: 28/5.2/0420
INDOBLOK 40: 28/5.2/0421

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Gulf Drug Company (Pty) Ltd
22 Burnside Drive
Old Mill Industrial Park
Mount Edgecombe, 4300

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

Date of the most recent amendment to the professional information as approved by the Authority: 21/06/2002
Date of registration: 29/12/1993