PATIENT INFORMATION LEAFLET

INDOBLOK 10 & INDOBLOK 40

Propranolol hydrochloride

10 mg or 40 mg per tablet

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

INDOBLOK 10 (Tablets)

INDOBLOK 40 (Tablets)

Read this entire leaflet carefully, before you start taking INDOBLOK, because it contains important information for you.

INDOBLOK is only available with a doctor's prescription for diagnosed conditions. **INDOBLOK** should be used carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **INDOBLOK** has been prescribed for you personally and you should not share this medicine, or any medication prescribed for you, with any other person. It may harm them, even if their symptoms are the same as yours.

WHAT DOES INDOBLOK CONTAIN?

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.

WHAT IS INDOBLOK USED FOR?

- Cardiac arrhythmias (abnormal heart beat)
- Treatment of high blood pressure
- Excessive production of thyroid hormone by the thyroid gland
- Phaeochromocytoma (tumour in the adrenal glands)
- Treatment of chest pain or discomfort
- Control of anxiety.

BEFORE TAKING INDOBLOK:

Do not take INDOBLOK:

- If you are allergic to propranolol or have ever had a harmful reaction to similar medications known as beta-blockers (e.g. atenolol, carvedilol, bisoprolol)
- If you are allergic to any of the other ingredients in **INDOBLOK**
- If you suffer with asthma or tightening of the chest
- If you suffer with excess acid production in your body (metabolic acidosis)
- If you have heart blockages
- If you have a slow heart rate
- If you have heart failure that does not respond to digitalis (e.g. digoxin)
- If you have high levels of urine in your blood
- If you are pregnant or breastfeeding your baby
- If you have low sugar
- If you suffer with Raynaud's Phenomenon (spasm of arteries causing reduced blood flow)
- If you suffer with odd circulation disorders (peripheral valve diseases).

Special caution should be taken with INDOBLOK:

- If you have congestive heart failure
- If you are diabetic
- If you suffer with and lung conditions or diseases

- If you have a second or third degree heart block
- If you have planned surgery.

Pregnancy and breastfeeding:

INDOBLOK is contraindicated during pregnancy and lactation.

If a pregnant mother uses **INDOBLOK** shortly before giving birth or during labour, it may result in the newborn baby being born with low sugar levels, having low muscle tone or collapsed (breathing difficulties).

INDOBLOK is distributed into breast milk.

If you are pregnant or breastfeeding, please consult your healthcare provider for advice before taking INDOBLOK.

Driving and using machinery:

INDOBLOK may make you feel sleepy or drowsy. This could affect your concentration and your safety when driving or operating dangerous machinery. You should not drive or operate machinery if you experience these effects. Caution is advised.

Important information about some of the ingredients in INDOBLOK:

INDOBLOK contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take **INDOBLOK.**

Using other medicines with INDOBLOK:

If **INDOBLOK** is taken at the same time as the medication listed below, unwanted side effects can be experienced.

- It can be dangerous to use **INDOBLOK** at the same time as hypoglycaemic agents (e.g. metformin, glimepiride), phenothiazines (e.g. chlorpromazine, fluphenazine) and various anti-arrhythmic agents (medication used to suppress abnormal heartbeats).
- Myocardial depressant agents (e.g. quinidine, lignocaine): Effects may be enhanced by **INDOBLOK.**
- Verapamil should not be used at the same time as **INDOBLOK** and neither of the two medicines should be used within several days of discontinuing the other.
- Calcium antagonists (e.g. amlodipine) should be used in caution when taken with **INDOBLOK**.
- Caution should be exercised when transferring from clonidine to **INDOBLOK**, as it may result in a hypertensive (high blood pressure) crisis.
- Beta-adrenergic stimulating agents (e.g. dobutamine, salbutamol) may diminish the effects of **INDOBLOK** and the hypotensive effects may dangerously be reversed.
- Use of **INDOBLOK** at the same time as alpha-adrenergic stimulating agents (e.g. noradrenaline) may lead to peripheral vasoconstrictor (blood vessel constriction) effects being enhanced.
- **INDOBLOK** may enhance some of the cardiac effects of digitalis and diminish others.

Always tell your healthcare provider if you are taking any other medicine. This includes complementary or traditional medicine.

HOW TO TAKE INDOBLOK:

Do not share medicines prescribed for you with any other person.

Always take **INDOBLOK** exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with **INDOBLOK** will last. Do not stop treatment early because it may affect your condition. If you have the impression that the effect of **INDOBLOK** is too strong or too weak, tell your doctor or pharmacist.

Tablets should preferably be taken before meals.

Adults:

The usual dose of **INDOBLOK** is 20 mg to 40 mg, three or four times a day.

For the treatment of hypertension, the dose may be increased up to 320 mg daily.

For use in phaeochromocytoma, 60 mg should be given daily for 3 days pre-operatively.

If you take more INDOBLOK than you should:

Overdosage of **INDOBLOK** can result in hypotension (low blood pressure), tightening of the chest or heart failure. You may feel lightheaded, dizzy or faint.

Treatment of an overdose requires supportive medical care.

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take INDOBLOK:

Do not take a double dose to make up for forgotten individual doses. It is important to take your **INDOBLOK** tablets regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, carry on with the next dose as normal.

POSSIBLE SIDE EFFECTS:

Like all medication, **INDOBLOK** can have side effects.

If any of the following side effects occur after you take **INDOBLOK**, discontinue use immediately and contact your healthcare provider or go to your nearest hospital:

- Allergic skin reactions (characterised by difficulty breathing, experience chest pain, wheezing and coughing, a rash, itching, facial swelling or feel faint)
- Hypoglycaemia (low blood sugar levels) or hypotension (low blood pressure)
- Transient hearing loss
- Hair loss
- Central nervous system effects, such as: vivid dreams, hallucinations, vision disturbances, nightmares or confusion
- Cold extremities
- Blood disorders
- Heart failure
- Parasthesia.

These are all serious side effects. You may need urgent medical attention.

The following, *frequent,* side effects have been reported either during clinical trials or during post-marketing experience:

- Nausea and/or vomiting
- Constipation or diarrhoea
- Fatigue or dizziness
- Dry eyes or mouth
- Muscle weakness or cramps
- Fluid retention.

If they continue or are severe, contact your doctor or pharmacist.

Not all side effects reported for INDOBLOK are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking INDOBLOK please consult your healthcare provider for advice.

STORAGE AND DISPOSAL OF INDOBLOK:

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.

Store **INDOBLOK** tablets in their original packaging. Do not use after the expiry date stated on the label. Do not store in a bathroom.

Return all unused or expired medicine to your pharmacist for safe disposal. Do not dispose of any medication in drains or toilets.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF INDOBLOK:

Plastic containers (HDPE/PP) containing 250 or 1000 tablets.

Patient ready packs (LDPE) of 28, 50, 56 or 84 tablets.

IDENTIFICATION OF INDOBLOK:

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

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

REGISTRATION NUMBERS:

INDOBLOK 10: 28/5.2/0420

INDOBLOK 40: 28/5.2/0421

NAME AND BUSINESS ADDRESS OF HOLDER OF CERTIFICATE OF REGISTRATION:

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

DATE OF PUBLICATION OF PATIENT INFORMATION LEAFLET:

Date of the most recent amendment to the patient information leaflet: 21/06/2002

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