

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

**INDERAL® 10, INDERAL® 40 Film-coated tablets**

**Propranolol hydrochloride**

**Contains sugar: lactose monohydrate**

**INDERAL 10: 79 mg/tablet**

**INDERAL 40: 147.4 mg/tablet**

**Read all of this leaflet carefully before you start taking INDERAL**

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

### **What is in this leaflet**

1. What INDERAL is and what it is used for
2. What you need to know before you take INDERAL
3. How to take INDERAL
4. Possible side effects
5. How to store INDERAL
6. Contents of the pack and other information

#### **1. What INDERAL is and what it is used for**

INDERAL belongs to a group of medicines called beta blockers.

INDERAL can be used for:

- raised blood pressure
- chest pain (angina)
- ensuring that the heart beats regularly
- protection of the heart after a heart attack
- prevention of migraine
- tremor

- anxiety
- certain thyroid conditions (overactive thyroid conditions)
- phaeochromocytoma [a tumour of special cells most often found in the middle of the adrenal gland], when used with other treatment.

## **2. What you need to know before you take INDERAL**

### **Do not take INDERAL:**

- If you are hypersensitive (allergic) to propranolol or any of the other ingredients of INDERAL (listed in section 6).
- If you have ever had asthma, chronic obstructive pulmonary disease, emphysema or wheezing disease, **DO NOT TAKE YOUR INDERAL**. Go back to your doctor or pharmacist.
- If you are pregnant or breast-feeding.
- If you ever had an allergic reaction to INDERAL or propranolol.
- If you have suffered or suffer from any heart condition, including heart failure, or heart block.
- If you have ever suffered from a very slow or very irregular heartbeat, very low blood pressure or very poor circulation.
- If you have ever suffered from a particular type of chest pain (angina) called Prinzmetal's angina.
- If you have ever been told that you have a phaeochromocytoma (a tumour of special cells most often found in the middle of the adrenal gland) which is not being treated with other medicines.
- After prolonged fasting

### **Warnings and precautions**

Take special care with INDERAL:

*Before taking INDERAL tell your doctor, pharmacist or other health care professional:*

- If you are fasting or have been fasting recently.
- If you have other health problems, such as with your kidneys, liver, diabetes, circulation disorders, heart problems, breathlessness or swollen ankles.
- If you frequently drink a lot of alcohol this may affect how INDERAL works.
- If you are taking clonidine for raised blood pressure or to prevent migraine, do not stop taking either your clonidine or INDERAL, without consulting your doctor.
- If you have diabetes, INDERAL may alter your response to insulin or other antidiabetic treatments. INDERAL can also modify your body's response to low blood sugar. Symptoms of increased heart

rate felt during episodes of low blood sugar may be reduced by INDERAL. Blood sugar may decrease to a very low level and result in fits or coma.

- INDERAL occasionally causes low blood sugar even in patients who do not suffer from diabetes e.g. the newborn, toddlers, children, elderly patients, patients with artificial kidneys or patients suffering from chronic liver disease and patients suffering from overdose.
- If you go to the hospital let the medical staff, and in particular the anaesthetist know (if you are having an operation) that you are taking INDERAL.
- Only stop taking INDERAL if your doctor tells you and then do so gradually.

### **Other medicines and INDERAL**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

In particular, tell your doctor if you are taking, or are about to stop taking medicines for:

- rizatriptan
- disopyramide, quinidine or propafenone or amiodarone (for irregular heartbeats)
- treatment for raised blood pressure or angina (in particular verapamil, diltiazem, clonidine, nifedipine, nisoldipine, nicardipine, isradipine, lacidipine, hydralazine).
- treatment for migraine which contain ergot derivatives
- chlorpromazine (for certain psychiatric disorders)
- indomethacin or ibuprofen (for pain relief), or other non-steroidal anti-inflammatory drugs (NSAIDs)
- treatment for heart failure (digoxin)
- treatment for stomach problems (cimetidine)
- treatment for tuberculosis (rifampicin)
- treatment for asthma (theophylline)
- treatment for prevention of blood clotting (warfarin)
- you should tell you doctor if you are taking any nasal decongestant or other cold remedies which you may have bought from a pharmacy.

### **INDERAL with food, drink and alcohol**

If you drink alcohol, please mention this to your doctor before you start to take INDERAL.

### **Pregnancy, breastfeeding and fertility**

<b>INDERAL should not be used during pregnancy and breast feeding.</b>
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If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

### **Driving and using machines**

INDERAL may make you feel drowsy/sleepy.

Do not drive because INDERAL could interfere with your ability to drive safely.

Do not operate any tools or machines.

### **INDERAL contains lactose monohydrate**

Your tablet contains lactose, which may cause a problem in a small number of patients who are intolerant to lactose.

### **3. How to take INDERAL**

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

Always take INDERAL exactly as your doctor or pharmacist has instructed you.

Check with your doctor or pharmacist if you are not sure.

The strength of INDERAL and the length of time you take them for will depend on what condition you are suffering from.

Swallow the tablet whole with half a glass of water.

Try to take your tablet at the same time every day.

Your doctor will tell you how long your treatment with INDERAL will last. Do not stop taking your tablets even if you are feeling better, unless your doctor tells you. Then only do so gradually.

If you have the impression that the effect of INDERAL is too strong or too weak, talk to your doctor or pharmacist, who may wish to change your treatment.

The table below shows the usual ranges of doses taken in 1 day for an adult. Often the dose is split throughout the day into smaller amounts:

<i>Raised blood pressure and Chest pain (angina)</i>	40 mg to 320 mg
Anxiety and Tremor	40 mg to 160 mg

Certain other heart conditions	30 mg to 160 mg
Irregular heart beats	30 mg to 240 mg
After a heart attack	180 mg to 240 mg
Prevention of migraine	30 mg to 160 mg
Certain thyroid conditions	30 mg to 160 mg
Phaeochromocytoma	30 mg to 60 mg

### **If you take more INDERAL than you should**

Propranolol is severely toxic if used in overdose. If you have accidentally taken more than the prescribed dose or are experiencing symptoms of overdose, you should urgently seek medical attention.

Overdose causes difficulty in breathing, low blood pressure, drowsiness, fits, an excessively slowed heartbeat or coma.

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

### **If you forget to take INDERAL**

If you miss a dose, take the dose as soon as you remember, but do not take your next dose at the same time. Then go on as before. Do not take a double dose to make up for forgotten individual doses.

## **4. Possible side effects**

INDERAL can have side effects.

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

Some people may develop a severe allergic reaction.

Tell your doctor if you notice any of the following side effects:

*Frequent side effects:*

- cold fingers and toes
- the heart beating more slowly

- numbness and spasm in the fingers which is followed by warmth and pain (Raunaud's phenomenon)
- disturbed sleep/nightmares
- fatigue

*Less frequent side effects:*

- diarrhoea
- nausea
- vomiting
- worsening of breathing difficulties, if you have or have had asthma
- breathlessness and/or swollen ankles if you also have heart failure
- heart block which may also cause an abnormal heartbeat, dizziness, tiredness or fainting
- dizziness particularly on standing up
- worsening of your blood circulation, if you already suffer from poor circulation
- hair loss
- mood changes
- confusion
- psychosis or hallucinations (disturbances of the mind)
- tingling of the hands
- disturbances of vision
- dry eyes
- skin rash, including worsening of psoriasis
- bruising more easily
- purple spots on the skin
- sexual dysfunction
- severe muscle weakness

Low levels of blood sugar may occur in diabetic and non-diabetic patients including the newborn, toddlers, children, elderly patients, patients with artificial kidneys or patients on medication for diabetes. It may also occur at fasting or in patients who have a chronic liver disease.

There may also be changes to some of the cells or other parts of your blood. It is possible that your doctor may take blood samples to check whether INDERAL has had any effect on your blood.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of INDERAL.

## **5. How to store INDERAL**

Store all medicines out of reach of children.

INDERAL 10: Store at or below 25 °C

INDERAL 40: Store at or below 30 °C

Store in the original container, tightly closed

Keep the container in the outer carton

Do not use INDERAL after the expiry date stated on the container

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What INDERAL contains**

The active substance is propranolol hydrochloride, tablets contain 10 mg or 40 mg.

The other ingredients are:

Calcium carboxymethylcellulose, carmine (E120), gelatin (E441), glycerol (E422), lactose, light magnesium carbonate (E504), magnesium stearate, methylhydroxypropylcellulose (E464), titanium dioxide (E171).

### **What INDERAL looks like and contents of the pack**

INDERAL 10:

Pink, round, biconvex, film-coated tablets, intagliated on one face with 10 and scored on the reverse face.

INDERAL 40:

Pink, round, biconvex, film-coated tablet, intagliated with Inderal 40 on one side and plain on the reverse side. The impressions are highlighted in white.

INDERAL 10 is packed in containers PVC-PVDC/Aluminium blister of 50 tablets.

INDERAL 40 is packed in HDPE containers of 50 tablets.

**Holder of Certificate of Registration**

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INDERAL 10: G/5.2/2863

INDERAL 40: G2864 (Act 101/1965)

**Access to the corresponding Professional Information**

In pack