

Final Approved Professional Information Leaflet (PIL)
for Medicines for Human Use
Prodorol 10/40 mg (Tablets)

SCHEDULING STATUS: S3

PRODOROL 10 mg/40 mg tablets

Propranolol

Contains tartrazine

Read all of this leaflet carefully before you start taking PRODOROL

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

1. WHAT PRODOROL is and what it is used for

PRODOROL belongs to a group of medicines called beta-blockers. PRODOROL contains the active ingredient substance propranolol and is used to:

- control irregular or fast heart beats (cardiac and supraventricular arrhythmias),
- treat high blood pressure,
- treat an overactive thyroid gland which causes an excess of thyroid hormone in the body (thyrotoxicosis),
- treat a tumour near the kidney (phaeochromocytoma),
- treat pain in the chest caused by blockages in the arteries (angina pectoris),
- control of increased heart-beat and tremor caused by anxiety or stress.

2. What you need to know before you take PRODOROL

Do not take PRODOROL

- if you are hypersensitive (allergic) to propranolol or any of the other ingredients of this PRODOROL (listed in section 6),
- if you are hypersensitive (allergic) to tartrazine,
- if you suffer from asthma or any other tightness of the chest or breathing problems,
- if you have increased acidity of the blood (metabolic acidosis), which is a complication of diabetes mellitus (low blood sugar levels),
- if you have heart block or heart conduction issues (atrioventricular block),
- if you have a slow heart rate (bradycardia),
- if you have heart failure,
- if you have high levels of urea in the blood (uraemia),
- if you are pregnant or breastfeeding,
- if you suffer from low blood sugar levels (hypoglycaemia),
- if you have decreased blood flow to your fingers and toes which may cause them to tingle or turn pale or blue (Raynaud's phenomenon),
- if you have a blood circulation disorder (peripheral vascular disease), which causes the blood vessels outside of your heart and brain to narrow, block or go into spasm,
- if you suffer from high blood pressure due to a tumour near your kidney (phaeochromocytoma).

Warnings and precautions

Take special care with PRODOROL if you:

- if you have a history of allergic reactions,
- if you have a tight chest,
- if you have heart weakness, heart failure or first degree heart block,
- if you suffer from Raynaud's disease/syndrome (cold sensation in fingers and toes) or intermittent claudication (narrowing of arteries in the legs causing pain on walking),
- if you have low blood sugar levels,
- if you have an over-active thyroid gland with symptoms of hyperthyroidism (increased appetite, weight loss, sweating),
- if you are taking PRODOROL, do not stop treatment suddenly, you should speak to your doctor to gradually reduce the dosage.

Other medicines and PRODOROL

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

Tell your doctor if you are taking or have been given the following medicines as they are known to interact with PRODOROL:

- adrenaline (epinephrine) (used in anaphylactic shock),
- lignocaine (a local anaesthetic),
- medicines to treat irregular heartbeat (arrhythmia) such as disopyramide, quinidine, flecainide, amiodarone, procainamide,
- medicines to treat heart diseases such as verapamil, diltiazem,
- medicines to treat heart conditions (digitalis glycosides) such as digoxin,
- medicines to prevent blood clotting such as warfarin,

- medicines to treat diabetes such as insulin,
- other medicines to treat high blood pressure such as alpha blockers, clonidine, moxonidine, methyldopa, levodopa, hydralazine or prazosin,
- medicines to clear excess water from the body (diuretics),
- ergotamine derivatives or rizatriptan (to treat migraine),
- barbiturates (to treat severe insomnia),
- chlorpromazine (for mental illness),
- cimetidine (to treat stomach ulcers),
- tricyclic anti-depressant, such as imipramine,
- monoamine-oxidase inhibitors, such as selegiline,
- non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, indomethacin,
- rifampicin (to treat infection),
- selective serotonin re-uptake inhibitors, such as fluvoxamine (to treat depression),
- theophylline (treating asthma and reversible airways obstruction),
- smoking tobacco.

PRODOROL with food

PRODOROL should be taken before meals.

Pregnancy and breastfeeding and fertility

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 PRODOROL.

Do not take PRODOROL if you are pregnant or breastfeeding.

If you become pregnant while you are taking this medicine, tell your doctor immediately, who will decide how you should be treated.

Driving and using machines

PRODOROL may cause visual disturbances, hallucinations, fatigue, mental confusion, dizziness or tiredness. Make sure you are not affected before you drive or operate machinery.

PRODOROL contains tartrazine

If you have been told by your doctor that you have an intolerance to tartrazine, contact your doctor before taking this medicine.

3. How to take PRODOROL

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

Always take PRODOROL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

- 20 mg to 40 mg three or four times a day. The dose may be increased up to 320 mg daily in the treatment of high blood pressure,
 - in phaeochromocytoma, 60 mg a day for 3 days before an operation.
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- The dose should be reduced in the elderly or patients with kidney impairment
 - Swallow the tablet preferably with a glass of water.
 - PRODOROL should be taken before meals.
 - Do not stop taking PRODOROL suddenly as this may worsen your condition. Speak to your doctor before you stop taking PRODOROL.

Your doctor will tell you how long your treatment with PRODOROL will last. If you have the impression that the effect of PRODOROL is too strong or too weak, tell your doctor or pharmacist.

If you take more PRODOROL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Don't forget to take your container with you. This could indicate how many tablets have been taken.

If you take more PRODOROL than you should

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

If you forget to take PRODOROL

Take it when you remember and carry on as before unless it is time for the next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking PRODOROL

Do not stop taking PRODOROL without talking to your doctor first, because you may experience a worsening of your condition and unpleasant side effects. Withdrawal should be gradual over 7 to 14 days.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

PRODOROL can have side effects.

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

If any of the following happens, stop taking PRODOROL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reaction such as itching, difficulty breathing or swelling of the face, lips, throat or tongue,
- intolerance to PRODOROL such as slow heart rate, and low blood pressure causing dizziness, light-headedness, fainting or blurred vision.

These are all very serious side effects. If you have them, you may have had a serious reaction to PRODOROL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- difficulty in sleeping, nightmares,
- slow heart rate,
- cold extremities such as cold hands and feet,
- Raynaud's syndrome (cold sensation in fingers and toes),
- tiredness.

Less frequent side effects

- low platelet count (thrombocytopenia),
- hallucinations, state of mental confusion (psychosis), mood changes, confusion, loss of memory, dizziness, feeling of 'pins and needles',
- disturbances in vision, dry eyes,
- worsening of heart failure, heart block, low blood pressure/fainting on standing,
- worsening of intermittent claudication (pain and/or cramp in the leg caused by reduced blood flow),
- patients with asthma or a history of breathing problems may experience difficulty in breathing,
- running stomach, nausea, vomiting,
- hair loss, dry flaky skin, worsening of psoriasis, skin rash,
- increase in antinuclear antibodies.

Frequency unknown:

- agranulocytosis (where bone marrow does not make enough neutrophils),
- signs of hyperthyroidism may be hidden,
- low blood sugar levels,
- changes in blood fats (cholesterol),
- depression, confusion,
- headache, fits (seizures),
- inflammation of the eyes causing red, sore, itching or weeping eyes (conjunctivitis),
- worsening of angina, heart failure,
- blood circulation disorder, gangrene (death of tissue as a result of loss of blood circulation, usually in the extremities),
- dyspnoea (shortness of breath),
- constipation, dry mouth,
- joint pain, muscle weakness,
- reduced blood flow to the kidneys,
- changes in sex drive or potency,

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 or 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 PRODOROL.

5. How to store PRODOROL

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original package.
- Do not use after the expiry date stated on the pack.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). Store all medicines out of reach and sight of children.

6. Contents of the pack and other information

What PRODOROL contains

- The active substance is propranolol. Each tablet contains 10 mg or 40 mg of propranolol.
- The other ingredients are: guava deep, ludipress, magnesium stearate and purified water.

What PRODOROL looks like and contents of the pack

PRODOROL 10 mg tablets: Round, biconvex pink scored tablets, 6,4 mm in diameter

PRODOROL 40 mg tablets: Round, biconvex pink scored tablets, 8,7 mm in diameter.

White, round, polypropylene securitainers with white LDPE caps containing 50, 250, 500 and 1000 tablets.

White LDPE patient ready packs of different pack sizes.

Not all pack sizes and types may be marketed.

Holder of Certificate of Registration

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