

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using INDERAL?

INDERAL contains the active ingredient propranolol hydrochloride. INDERAL is used to treat or prevent a number of conditions, most of which are related to the heart. For more information, see Section 1. Why am I using INDERAL? in the full CMI.

2. What should I know before I use INDERAL?

Do not use if you have ever had an allergic reaction to propranolol hydrochloride or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I use INDERAL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INDERAL and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use INDERAL?

- Your doctor will tell you what dose to take.
- More instructions can be found in Section 4. How do I use INDERAL? in the full CMI.

5. What should I know while using INDERAL?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using INDERAL. If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking INDERAL. Call your doctor straight away if you have a severe allergic reaction to foods, medicines or insect stings, feel light-headed, dizzy or faint, and this problem gets worse or continues, plan to have surgery (even at the dentist) that needs a general anaesthetic or become pregnant while taking INDERAL.
Things you should not do	 Do not give INDERAL to anyone else even if they have the same condition as you. Do not use INDERAL to treat any other complaints unless your doctor tells you to. Do not stop taking INDERAL without checking with your doctor.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how INDERAL affects you.
Drinking alcohol	 Tell your doctor if you drink alcohol. Alcohol may increase the effects of INDERAL.
Looking after your medicine	 Tablet bottle (10 mg): Store below 30°C. Protect from light. Tablet bottle (40 mg) and blister pack (10 and 40 mg): Store below 25°C. Protect from light. Store in a cool, dry place, within the original container, away from young children.

For more information, see Section 5. What should I know while using INDERAL? in the full CMI.

6. Are there any side effects?

Common side effects include: nausea (feeling sick), vomiting, loss of appetite, diarrhoea, stomach pain, flatulence, cold hands or feet, dizziness, tiredness, rash, flushing, hair loss, feeling tired, lethargic or lack of energy. Serious side effects include: depression, disturbed sleep, vivid dreams or nightmares, conjunctivitis, dry eyes, visual disturbances, trouble passing urine, unexplained bruising, mood changes, confusion, sexual problems, loss of hearing or slow heart beats. Very serious side effects include: extreme tiredness or breathlessness on mild exercise, wheezing, difficulty breathing or an asthma attack or fast heart beats (palpitations).

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

INDERAL®

Active ingredient(s): propranolol hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using INDERAL. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using INDERAL.

Where to find information in this leaflet:

- 1. Why am I using INDERAL?
- 2. What should I know before I use INDERAL?
- 3. What if I am taking other medicines?
- 4. How do I use INDERAL?
- 5. What should I know while using INDERAL?
- <u>6.</u> <u>Are there any side effects?</u>
- 7. Product details

1. Why am I using INDERAL?

INDERAL contains the active ingredient propranolol hydrochloride. INDERAL belongs to a group of medicines called beta-blockers. It works by affecting the body's response to some nerve impulses, especially in the heart.

As a result, it decreases the heart's need for blood and oxygen and therefore reduces the amount of work the heart has to do. It also widens the blood vessels in the body, as well as helping the heart to beat more regularly.

INDERAL is used to treat or prevent a number of conditions, most of which are related to the heart:

- to lower high blood pressure, also called hypertension
- to prevent angina
- to treat or prevent heart attacks, or reduce your risk of heart problems following a heart attack
- to treat irregularities in heart beat, including those caused by anxiety
- essential tremor (shaking of head, chin, hands)
- phaeochromocytoma
- Fallot's Tetralogy
- to prevent migraine headaches

2. What should I know before I use INDERAL?

Warnings

Do not use INDERAL if:

- you are allergic to propranolol hydrochloride, or any of the ingredients listed at the end of this leaflet.
- you are allergic to other similar medicines such as beta blockers. Always check the ingredients to make sure you can use this medicine.
- you have asthma or severe breathing problems.
- you have certain other heart problems for example heart failure, low blood pressure, problems with your circulation, Prinzmetal's angina, or a slow heart beat.
- you have low blood sugar levels.

Taking INDERAL may make these conditions worse.

Check with your doctor if you:

- have any other medical conditions, including
 - o asthma or serious breathing problems
 - o heart problems
 - o low blood pressure
 - o problems with your circulation
 - o diabetes or low blood sugar
 - o an overactive thyroid gland
 - o liver problems
 - o kidney problems
- take any medicines for any other condition
- have allergies to any other medicines, food, preservatives or dyes.
- are fasting, or have been fasting recently

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

It may affect your baby if you take it at any time during your pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your baby can take in INDERAL from breast milk if you are breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with INDERAL and affect how it works, and some medicines may be affected by INDERAL. These medicines include:

- calcium channel blockers medicines used to treat high blood pressure
- digoxin a medicine used to treat heart failure
- medicines for migraine
- medicines for diabetes
- warfarin a medicine that stops blood clots
- theophylline a medicine used to treat asthma
- rifampicin a medicine used to treat tuberculosis
- ibuprofen, indomethacin medicines used to treat pain and inflammation
- cimetidine a medicine used to treat ulcers
- chlorpromazine a medicine used to treat psychotic illnesses

 rizatriptan - a medicine used to treat migraine headaches

You may need to use different amounts of your medicines or take different medicine. Your doctor will advise you. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking INDERAL.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect INDERAL.

4. How do I use INDERAL?

How much to take

- For high blood pressure:
 - o The usual starting dose is one 40 mg tablet taken twice a day for one week.
 - o The dose is then usually increased to between 120 mg to 320 mg daily.
 - If you are taking other medicines which lower blood pressure, your doctor may need to change the dose of them to obtain the best results for you.
- For angina and tremor:
 - o The usual dose is 40 mg taken two or three times a day.
- To treat or prevent heart attack
 - The usual dose is 80 mg taken twice a day, often starting with 40 mg taken four times a day for 2 or 3 days
- For migraine prevention
 - o Adults: The usual dose is 40 mg taken twice a day. This may need to be increased up to 80 mg twice a day.
 - Children over 7 years: The starting dose is 10 mg taken once or twice daily. This can be increased if necessary.
- Other conditions
 - o Your doctor will tell you what dose to take.
 - Follow the instructions provided and use INDERAL until your doctor tells you to stop.

When to take INDERAL

- INDERAL should be used regularly at the same time each day.
- If you forget to use INDERAL
- If it is almost time for your next dose (within 6 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise take it as soon as you remember and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

 If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much INDERAL

If you think that you have used too much INDERAL, you may need urgent medical attention. INDERAL is severely toxic if you take too much. Taking too much causes difficulty in breathing, light-headedness or dizziness, feeling very tired, fits, slowed heart beat or coma.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using INDERAL?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking INDERAL.

Tell any doctors, dentists, and pharmacists who are treating you that you are taking this medicine

Call your doctor straight away if you:

- Have a severe allergic reaction to foods, medicines or insect stings
 - If you have a history of allergies, there is a chance that INDERAL may cause allergic reactions to be worse and harder to treat.
- feel light-headed, dizzy or faint, and this problem gets worse or continues
 - o get up slowly when getting out of bed or standing up
 - o You may feel light-headed or dizzy when you begin to take INDERAL.
 - o Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure.
- plan to have surgery (even at the dentist) that needs a general anaesthetic
 - o Your blood pressure may drop suddenly if INDERAL interacts with the anaesthetic.
- become pregnant while taking INDERAL
- have diabetes and notice any blood sugar level changes
 - INDERAL may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (hypoglycaemia) such as increased heart rate.

- INDERAL may increase the time your body takes to recover from low blood sugar. Your doses of diabetic medicines, including insulin, may need to change.
- do not have diabetes and notice a low blood sugar (hypoglycaemia)
 - These may include the newly born, toddlers, children, elderly, patients suffering from overdose, patients suffering from chronic liver disease, fasting patients or patients on haemodialysis.
- Remind any doctor, dentist or pharmacist you visit that you are using INDERAL.

Things you should not do

- Do not give INDERAL to anyone else even if they have the same condition as you.
- Do not use INDERAL to treat any other complaints unless your doctor tells you to.
- Do not stop taking INDERAL without checking with your doctor. Your doctor may want you to gradually reduce the amount of INDERAL you are taking before stopping completely. This may help reduce the possibility of your condition getting worse.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how INDERAL affects you.

INDERAL may cause dizziness, light-headedness, tiredness, or drowsiness in some people. Make sure you know how you react to INDERAL before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may increase the effects of INDERAL. Dizziness or light-headedness may be worse.

Things to be careful of

Dress warmly during cold weather, especially if you will be outside for a long time (for example when playing winter sports).

INDERAL, like other beta-blocker medicines, may make you more sensitive to cold temperatures, especially if you have circulation problems.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

Looking after your medicine

Keep your tablets in the original container until it is time to take them.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 30°C (10 mg tablet bottle) and below 25°C (40 mg

tablet bottle, 10 mg blister pack, and 40 mg blister pack), away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gut-related: • nausea (feeling sick), vomiting • loss of appetite • diarrhoea, stomach pain, flatulence Other:	Speak to your doctor if you have any of these less serious side effects and they worry
 cold hands or feet dizziness, tiredness rash, flushing hair loss feeling tired, lethargic, lack of energy 	you.

Serious side effects

Serious side effects	What to do
Head-related: depression disturbed sleep, vivid dreams or nightmares visual disturbances mood changes, confusion loss of hearing Other: unexplained bruising sexual problems slow heart beats conjunctivitis, dry eyes trouble passing urine	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Very Serious side effects

Very serious side effects	What to do
Allergic reaction-related: extreme tiredness or breathlessness on mild exercise wheezing, difficulty breathing or an asthma attack fast heart beats (palpitations)	Stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What INDERAL contains

Active ingredient (main ingredient)	Propranolol hydrochloride
Other ingredients	Lactose monohydrate
(inactive ingredients)	Carmellose calcium Gelatine
	Magnesium stearate
	Glycerol
	Hypromellose
	Titanium dioxide
	Carmine
Potential allergens	None.

Do not take this medicine if you are allergic to any of these ingredients.

What INDERAL looks like

INDERAL tablets are pink, film coated and biconvex.

INDERAL 10 mg is intagliated on one face with 10 and bisected on the reverse face. AUST R 11228 and 474025.

INDERAL 40 mg is intagliated on one face with 40 and bisected on the reverse face. AUST R 11230 and 474026.

Inderal tablets are supplied in HDPE bottles and PVC/PVDC/Al blister packs of 100 tablets.

Who distributes INDERAL

Clinect Pty Ltd 120 - 132 Atlantic Drive Keysborough VIC 3173 Australia

Free Call Australia: 1800 899 005

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