

DERALIN®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking DERALIN?

DERALIN contains the active ingredient propranolol hydrochloride. DERALIN 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 taking DERALIN?](#) in the full CMI.

2. What should I know before I take DERALIN?

Do not take it 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 take DERALIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DERALIN 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 take DERALIN?

- Take DERALIN as prescribed by your doctor. The dose depends on your condition and whether you are taking other medicines.

More instructions can be found in Section [4. How do I take DERALIN?](#) in the full CMI.

5. What should I know while taking DERALIN?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking DERALIN.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking DERALIN.
- **Call your doctor straight away if you have a severe allergic**

	<p>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 DERALIN.</p>
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not give DERALIN to anyone else even if they have the same condition as you. ● Do not use DERALIN to treat any other complaints unless your doctor tells you to. ● Do not stop taking DERALIN without checking with your doctor.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful before you drive or use any machines or tools until you know how DERALIN affects you.
<p>Drinking alcohol</p>	<ul style="list-style-type: none"> ● Tell your doctor if you drink alcohol.

	<ul style="list-style-type: none"> • Alcohol may increase the effects of DERALIN.
Looking after your medicine	<ul style="list-style-type: none"> • Store below 30°C in a cool, dry place away from young children. • Keep your medicine in the bottle until it is time to take them.

For more information, see Section [5. What should I know while taking DERALIN?](#) in the full CMI.

6. Are there any side effects?

Less serious 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, slow or irregular 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.

DERALIN®

Active ingredient: *propranolol hydrochloride*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I taking DERALIN?](#)
- [2. What should I know before I take DERALIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take DERALIN?](#)
- [5. What should I know while taking DERALIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking DERALIN?

DERALIN contains the active ingredient propranolol hydrochloride. DERALIN 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.

DERALIN 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 or heart rhythm, including those caused by anxiety or an overactive thyroid gland
- to treat essential tremor (shaking of head, chin, hands)
- to treat phaeochromocytoma, a rare tumour of the adrenal gland (only when used in combination with another medicine)
- to treat Fallot's Tetralogy, a congenital heart disease
- to prevent migraine headaches

Ask your doctor if you have any questions about why DERALIN has been prescribed for you.

Your doctor may have prescribed DERALIN for another reason.

2. What should I know before I take DERALIN?

Warnings

Do not take DERALIN if you:

- are allergic to propranolol hydrochloride, or any of the ingredients listed at the end of this leaflet.
- are allergic to other similar medicines such as beta-blockers. Always check the ingredients to make sure you can take this medicine.

Some of the symptoms of an allergic reaction may include:

- wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- rash, itching or hives on the skin
- fast heart beat (palpitations)
- extreme tiredness or breathlessness on mid exercise.

Taking DERALIN may make these conditions worse.

Check with your doctor if you:

- have any of the following medical conditions, including
 - asthma or serious breathing problems
 - heart problems including angina
 - low blood pressure
 - problems with your circulation

- diabetes or a history of low blood sugar
 - an overactive thyroid gland
 - liver problems
 - kidney problems
 - any medical condition affecting your blood vessels or circulation
- take any medicines for any other condition
 - have allergies to any other medicines, food, preservatives or dyes
 - are fasting or have been fasting recently
 - plan to have surgery, including dental surgery, especially if it requires a general anaesthetic

If you have not told your doctor any of the above, tell them before you start taking DERALIN.

Your doctor may want to take special care if you have any of these conditions.

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.

DERALIN should not be taken during pregnancy unless advised by your doctor.

This medicine like other medicines in its group have been associated with unwanted effects in the unborn or newborn baby.

Check with your doctor if you are breastfeeding or intend to breastfeed.

DERALIN should not be taken if you are breastfeeding unless advised by your doctor.

Like other beta-blocker medicines, your baby can take in DERALIN from the breast milk if you are breastfeeding. Breastfeeding is not recommended while taking DERALIN.

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 DERALIN and affect how it works, and some medicines may be affected by DERALIN These medicines include:

- calcium channel blockers - medicines used to treat high blood pressure, angina and other heart conditions, such as verapamil, diltiazem, nifedipine
- digoxin - a medicine used to treat heart failure
- medicines for migraines such as ergotamine, dihydroergotamine, rizatriptan
- medicines used to treat diabetes including insulin
- warfarin - a medicine that stops blood clots

- theophylline - a medicine used to treat asthma
- rifampicin - a medicine used to treat tuberculosis
- ibuprofen, indomethacin - medicine used to treat pain, arthritis or inflammation
- cimetidine - a medicine used to treat reflux and stomach ulcers
- chlorpromazine and thioridazine - medicines used to treat psychiatric disorders
- adrenaline (epinephrine) - a medicine used in emergency situations

You may need to take 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 DERALIN.

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

4. How do I take DERALIN?

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your pharmacist.

How much to take

- For high blood pressure:

- The usual starting dose is one 40 mg tablet taken twice a day for one week.
- 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:
 - 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
 - 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
 - Your doctor will tell you what dose to take.
 - Your doctor may tell you to take a different amount of DERALIN to the one given in this leaflet.
 - Follow your doctors' instructions carefully until your doctor tells you to stop.

How to take DERALIN

- Swallow the tablets with a glass of water.

When to take DERALIN

- DERALIN should be taken regularly at the same time each day.
- DERALIN can be taken with or without food.

How long to take DERALIN for

- Keep taking DERALIN for as long as your doctor recommends. Do not stop taking DERALIN, or lower the dose, without checking with your doctor.

If you forget to take DERALIN

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 are not sure what to do, ask your doctor or pharmacist.
- If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much DERALIN

If you think that you or anyone else has taken too much DERALIN, urgent medical attention may be needed.

DERALIN is severely toxic if you take too much. If you take too much DERALIN, you may have difficulty breathing, light-headedness or dizziness, feeling very tired, fits, have a slow heart beat, or coma.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 taking DERALIN?

Things you should do

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking DERALIN.**
- Tell any doctors, dentists, and pharmacists who are treating you that you are taking this medicine.
- Since DERALIN is meant to be taken regularly every day, keep a continuous supply of medicine so

you don't run out, especially over weekends or on holidays.

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 DERALIN may cause allergic reactions to be worse and harder to treat.
- feel light-headed, dizzy or faint, and this problem gets worse or continues.
 - You may feel light-headed, dizzy or faint when you begin to take DERALIN.
 - Get up slowly when getting out of bed or standing up. 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.
 - Your blood pressure may drop suddenly if DERALIN interacts with the anaesthetic.
- become pregnant while taking DERALIN.
- have diabetes and notice any blood sugar level changes
 - DERALIN 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.
 - DERALIN may prolong the blood glucose lowering effect of your diabetic medicine or 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 taking DERALIN.

Visit your doctor regularly so they can check on your progress.

Things you should not do

- Do not give DERALIN to anyone else even if they have the same condition as you.
- Do not take DERALIN to treat any other complaints unless your doctor tells you to.
- Do not stop taking DERALIN without checking with your doctor.
 - Stopping DERALIN suddenly may worsen your angina or cause other heart complications to occur. Your doctor will tell you how to gradually reduce the amount of DERALIN 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 DERALIN affects you.

DERALIN may cause dizziness light-headedness, tiredness, or drowsiness in some people. Make sure you know how you react to DERALIN 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 DERALIN. Dizziness or light-headedness may be worse.

Things to be careful of

Make sure you drink enough water in hot weather and during exercise, especially if you sweat a lot.

If you do not drink enough water while taking DERALIN, you may feel faint, lightheaded or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

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

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

Looking after your medicine

- Keep your tablets in the bottle until it is time to take them.
- Store below 30°C.

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

Store it in a cool dry place 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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

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

Do not take this medicine after the expiry date or if the packaging shows signs of tampering or the tablets do not look quite right.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DERALIN, even if you do not think that it is connected with the medicine.

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
<p>Gut-related:</p> <ul style="list-style-type: none">• nausea (feeling sick), vomiting• loss of appetite• diarrhoea, stomach pain, flatulence <p>Other:</p> <ul style="list-style-type: none">• cold hands or feet• dizziness, tiredness• rash, flushing• hair loss	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • feeling tired, lethargic, lack of energy 	

Serious side effects

Serious side effects	What to do
<p>Head-related:</p> <ul style="list-style-type: none"> • depression • disturbed sleep, vivid dreams or nightmares • visual disturbances • mood changes, confusion • loss of hearing <p>Other:</p> <ul style="list-style-type: none"> • unexplained bruising • sexual problems • conjunctivitis, dry eyes • trouble passing urine 	<p>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.</p>

Very serious side effects

Very serious side effects	What to do
<p>Allergic reaction-related:</p>	<p>Stop taking this medicine and tell your doctor immediately,</p>

Very serious side effects	What to do
<ul style="list-style-type: none"> ● extreme tiredness or breathlessness on mid exercise, which may occur together with swelling of feet or legs due to fluid build-up ● chest tightness, wheezing, difficulty breathing or an asthma attack ● fast, slow or irregular heart beats (palpitations) ● any type of skin rash ● swelling of the face, lips, tongue or throat which may cause difficulty in swallowing 	<p>or go to Accident and Emergency at your nearest hospital.</p>

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.

DERALIN is not addictive.

What DERALIN contains

Active ingredient (main ingredient)	propanol hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• calcium carbonate• croscarmellose sodium• gelatin• pregelatinised maize starch• magnesium stearate• Opadry Red OY-7601
Potential allergens	sulfites

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

What DERALIN looks like

DERALIN comes in 10 mg, 40 mg and 160 mg tablet strengths.

DERALIN 10 mg: round red tablet marked "PP/10" on one side and "G" on the other.

Each bottle contains 100 tablets.

AUST R 17612

DERALIN 40 mg: round red tablet marked "PP/40" on one side and "G" on the other.

Each bottle contains 100 tablets.

AUST R 17614

DERALIN 160 mg: round red tablet marked "PP/160" on one side and "G" on the other.

Each bottle contains 50 tablets.

AUST R 17613

Who distributes DERALIN

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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