

DERALIN®

contains the active ingredient *propranolol hydrochloride*

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DERALIN.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking DERALIN against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What DERALIN is used for

DERALIN 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 contains the active ingredient propranolol hydrochloride, which belongs to a group of medicines called beta-blockers.

DERALIN is used to treat or prevent a number of conditions. These include:

- hypertension (high blood pressure)
- angina
- heart beat or heart rhythm irregularities, including those caused by anxiety or an overactive thyroid gland
- essential tremor (shaking of head, chin, hands)
- phaeochromocytoma, a rare tumour of the adrenal gland (only when used in combination with another medicine)
- heart attack prevention or treatment, or to reduce the risk of heart problems after a heart attack
- Fallot's Tetralogy
- migraine headache prevention.

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.

DERALIN is not addictive.

DERALIN is available only with a doctor's prescription.

Before you take DERALIN

When you must not take it

Do not take DERALIN if you are allergic to:

- propranolol hydrochloride
- any of the ingredients listed at the end of this leaflet
- any other similar medicines such as beta-blockers

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- fast heart beat (palpitations)

- extreme tiredness or breathlessness on mild exercise
- skin rash, itching or hives
- swelling of the face, lips or tongue or other parts of the body.

Do not take DERALIN if you have asthma or severe breathing problems.

Taking DERALIN may make these conditions worse.

Do not take DERALIN if you have certain other heart problems for example heart failure, low blood pressure, problems with your circulation, Prinzmetal's angina or a slow heartbeat.

Taking DERALIN may make these conditions worse.

Do not take DERALIN if you have low blood sugar levels.

Taking DERALIN may make these conditions worse.

Do not take DERALIN if you are receiving:

- emergency treatment for shock or severely low blood pressure
- certain anaesthetics for medical or dental procedures.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in DERALIN passes into breast milk (if applicable) and there is a possibility that your baby may be affected.

Do not take DERALIN if the expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date, it may not work as well.

Do not take DERALIN if the packaging shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

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

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

Tell your doctor if you are breastfeeding or wish to breastfeed.

Like other beta-blocker medicines, DERALIN passes into breast milk and is not recommended for use during breastfeeding.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- asthma or serious breathing problems
- heart problems including angina
- low blood pressure
- an overactive thyroid gland
- diabetes or a history of low blood sugar
- kidney problems

- liver problems
- any medical condition affecting your blood vessels or circulation.

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

Tell your doctor if you are fasting or have been fasting recently.

Tell your doctor if you plan to have surgery, including dental surgery, especially if it requires a general anaesthetic.

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

Taking other medicines

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

Some medicines may be affected by DERALIN, or may affect how well it works. These 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
- medicines used to treat arthritis, pain or inflammation such as ibuprofen or indometacin
- warfarin, a medicine used to prevent blood clots
- cimetidine, a medicine used to treat reflux and stomach ulcers
- theophylline, a medicine used to treat asthma
- chlorpromazine and thioridazine, medicines used to treat psychiatric disorders
- rifampicin, an antibiotic used to treat tuberculosis
- adrenaline (epinephrine), a medicine used in emergency situations.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking DERALIN.

How to 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 doctor or 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 doctor's instructions carefully.

How to take DERALIN

Swallow the tablets with a glass of water.

When to take DERALIN

DERALIN can be taken with or without food.

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 the missed dose 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.

How long to take DERALIN for

To properly control your condition, DERALIN must be taken every day.

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 take too much DERALIN (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (Australia telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much DERALIN.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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.

While you are taking DERALIN

Things you must do

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

Tell any other doctors, dentists and pharmacists who are treating you that you are taking DERALIN.

If you become pregnant while taking DERALIN, tell your doctor immediately.

If you have or have had a severe allergic reaction to foods, medicines or insect stings, tell your doctor immediately.

If you have a history of allergies, there is a chance that DERALIN may cause allergic reactions to be worse and harder to treat.

If you plan to have surgery (including dental surgery) that requires a general anaesthetic, tell your doctor or dentist that you are taking DERALIN.

Your blood pressure may drop suddenly if DERALIN interacts with the anaesthetic.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

You may feel light-headed or dizzy when you begin to take DERALIN.

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. If this problem gets worse or continues, talk to your doctor.

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.

If you are being treated for diabetes, make sure you check your blood glucose level regularly and report any changes to your doctor.

DERALIN may affect how well your diabetes is controlled. DERALIN may hide some signs of low blood glucose levels (hypoglycaemia) such as increased heart rate.

It may also prolong the blood glucose lowering effect of your diabetic medicine or increase the time it takes for your body to recover from low blood glucose. Your doctor therefore may need to adjust the dose of your insulin or diabetic medicines.

Non-diabetic patients:

DERALIN may also occasionally cause low blood sugar (hypoglycaemia) in non-diabetic patients.

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.

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

Things you must not do

Do not stop taking DERALIN, or lower the dose, 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.

Do not use DERALIN to treat any other conditions unless your doctor tells you to.

Do not give DERALIN to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how DERALIN affects you.

DERALIN is unlikely to affect your ability to drive or operate machinery. However, as dizziness, light-headedness, drowsiness or fatigue have occasionally occurred in some people, do not drive, operate machinery or do anything else that could be dangerous until you know how DERALIN affects you.

Be careful drinking alcohol while taking DERALIN.

Combining DERALIN and alcohol can make you more dizzy or lightheaded. Alcohol can also increase the effects of DERALIN.

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.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DERALIN.

DERALIN helps most people and is usually well tolerated, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- tiredness
- dizziness
- sleeping problems, nightmares
- rash, flushing
- hair loss
- feeling tired, lethargic, lack of energy
- feeling sick (nausea), vomiting
- cold hands or feet
- diarrhoea
- flatulence
- stomach pain
- loss of appetite.

The above list includes the milder side effects of DERALIN.

Tell your doctor immediately if you notice any of the following:

- dry or irritated eyes, blurred vision, conjunctivitis
- difficulty hearing
- unusual bleeding or bruising under the skin
- changes in mood such as depression, confusion, hallucinations
- sexual problems
- trouble passing urine
- slow heart beats
- disturbed sleep, vivid dreams or nightmares

The above list includes serious side effects which may require medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- any type of skin rash
- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing
- chest tightness, difficulty breathing, wheezing, asthma attack
- fast, slow or irregular heart beat
- shortness of breath (sometimes with tiredness, weakness and reduced ability to exercise), which may occur together with swelling of the feet or legs due to fluid build-up.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

This medicine may cause low blood sugar levels (hypoglycaemia) in some people.

This may occur in people being treated with insulin and other medicines for diabetes, but occasionally can also occur in the newly born, infants, children, the elderly, people who are fasting, undergoing haemodialysis, suffering from chronic liver disease or from an overdose.

Tell your doctor if you notice anything that is making you feel unwell.

This is not a complete list of all possible side effects.

Other side effects not listed above may also occur in some people.

After taking DERALIN

Storage

Keep DERALIN where children cannot reach it.

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

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

If you take the tablets out of the bottle they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store DERALIN or any other medicine in the bathroom or near a sink.

Do not leave DERALIN in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking DERALIN, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

DERALIN tablets are available in 3 strengths:

- DERALIN 10 - round red tablet marked "PP/10" on one side and "G" on the other. Each bottle contains 100 tablets.
- DERALIN 40 - round red tablet marked "PP/40" on one side and "G" on the other. Each bottle contains 100 tablets.
- DERALIN 160 - round red tablet marked "PP/160" on one side and "G" on the other. Each bottle contains 50 tablets.

Ingredients

The active ingredient in DERALIN is propranolol hydrochloride.

- Each DERALIN 10 tablet contains 10 mg of propranolol hydrochloride.
- Each DERALIN 40 tablet contains 40 mg of propranolol hydrochloride.
- Each DERALIN 160 tablet contains 160 mg of propranolol hydrochloride.

The tablets also contain the following inactive ingredients:

- calcium carbonate
- croscarmellose sodium
- gelatin
- pregelatinised maize starch
- magnesium stearate
- Opadry Red OY-7601.

DERALIN tablets contain sulfites.

Manufacturer

DERALIN is made in Australia by:

Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatrix.com.au
Phone: 1800 274 276

Australian registration numbers:

DERALIN 10 - AUST R 17612
DERALIN 40 - AUST R 17614
DERALIN 160 - AUST R 17613

DERALIN ® is a Viatrix company trade mark

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