

Rapiblyk®

Contains landiolol hydrochloride 300 mg per vial

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.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why is Rapiblyk being used ?

Rapiblyk contains the active ingredient landiolol hydrochloride. Rapiblyk is used as a short-term treatment for irregular heartbeat before, during or after surgery. It is also used in emergency situations.

For more information, see Section [1. Why is Rapiblyk being used?](#) in the full CMI.

2. What should I know before Rapiblyk is used?

Do not use if you have ever had an allergic reaction to landiolol 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 Rapiblyk is used?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with landiolol hydrochloride 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 is Rapiblyk used?

Rapiblyk must only be given by a doctor or nurse. The powder for injection is reconstituted and the final solution must be given as a slow infusion into a vein.

More instructions can be found in Section [4. How is Rapiblyk used?](#) in the full CMI.

5. What should I know while Rapiblyk is being used?

Driving or using machines	<ul style="list-style-type: none"> Be careful before you drive or use any machines or tools until you know how Rapiblyk affects you.
Drinking alcohol	<ul style="list-style-type: none"> Do not drink alcohol if your doctor plans to administer Rapiblyk. If you drink alcohol while you are being given Rapiblyk your blood pressure may drop, making you feel dizzy and faint.
Looking after the medicine	<ul style="list-style-type: none"> This medicine will be stored in the pharmacy or on the ward of a hospital. The injection is kept in a cool dry place, where it is protected from light and the temperature stays below 25°C.

For more information, see Section [5. What should I know while Rapiblyk is being used?](#) in the full CMI.

6. Are there any side effects?

Rapiblyk may cause headache, slow heartbeat, atrial fibrillation, cardiac arrest, low blood pressure, collapse, nausea (feeling sick), vomiting, pneumonia, breathing problems, liver problems and fever.

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Rapiblyk®

Active ingredient: landiolol hydrochloride

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Rapiblyk?

Rapiblyk contains the active ingredient landiolol hydrochloride.

Rapiblyk is used as a short-term treatment for irregular heartbeat before, during or after surgery. It is also used in emergency situation.

Irregular heartbeat, also known as arrhythmia, means that there is a disturbance of the heart's normal rhythm or beat. Arrhythmia may be caused by a number of factors, including some heart diseases, an overactive thyroid gland, or chemical imbalances. Rapiblyk helps restore the heart's normal rhythm.

Rapiblyk belongs to a group of medicines called beta-blockers.

Your doctor will have explained why you are being treated with Rapiblyk and what dose you will be given.

Follow all the directions and advice given to you by your doctor carefully.

Your doctor may have prescribed for uses other than those listed above.

2. What should I know before Rapiblyk is used?

Warnings

Do not use Rapiblyk if:

- you are allergic to landiolol hydrochloride or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are allergic to any other beta-blocker medicine
- you have a very slow or irregular heart beat (less than 50 beats per minute).
- you have a fast or alternating fast and slow heartbeat.
- you have heart disease or certain other heart conditions.
- you are taking certain heart medicines, called calcium channel blockers or calcium antagonists, such as verapamil or diltiazem.
- you are receiving emergency treatment for shock or severely low blood pressure.
- you have a problem called "severe heart block". Heart block is a problem with the electrical messages that control your heartbeat.
- you have serious heart failure symptoms.
- you have increased pressure in the lungs (pulmonary hypertension).
- you have a gland disease called phaeochromocytoma which has not been treated.
- you have asthma symptoms that are worsening rapidly.
- you have very high levels of acids in your body (severe metabolic acidosis) which cannot be corrected.

You should not be given Rapiblyk if the solution is discoloured, cloudy, turbid, or particles or a precipitate is present.

The solution is normally a clear and colourless liquid practically free from visible particles.

You should not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If this medicine is used after the expiry date it may not work as well.

Check with your doctor if you:

- have any allergies or you are at risk of anaphylactic reactions (severe allergic reactions). Rapiblyk can make allergies more severe and more difficult to treat.
- have or have had any of the following medical conditions:
 - low blood pressure
 - any other heart problem

- asthma, wheezing, difficulty breathing or other lung problems
- diabetes
- low sugar levels in the blood
- kidney problems.
- circulation problems, such as paleness of your fingers or aching, tired and sometimes burning pains in your legs

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.

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

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 Rapiblyk and affect how it works.

Such medicines may include:

- medicines used to treat heart rhythm problems (such as diltiazem, verapamil, propafenone, disopyramide, amiodarone, digoxin, digitalis), beta-blockers and high blood pressure (such as nifedipine)
- medicines used to treat diabetes, including insulin and medicines taken by mouth
- medicines usually used during an operation to relax your muscles (such as suxamethonium) or medicines used to reverse the effect of muscle relaxants called cholinesterase inhibitors (such as neostigmine, distigmine, edrophonium). Your doctor will also take special care when using Rapiblyk during operations, when you will be having anaesthetics and other treatments.
- medicines used as pain killers, such as non-steroidal anti-inflammatory drugs known as NSAIDs
- amisulpride, a medicine that is used to treat schizophrenic disorders.
- tricyclic antidepressant medicines (such as imipramine and amitriptyline).
- barbiturates (such as phenobarbital, used to treat epilepsy).
- phenothiazines (such as chlorpromazine, used to treat mental disorders).
- medicines used to treat asthma.
- medicines that can lower the blood pressure (such as clonidine).
- adrenaline (epinephrine), which is used to treat allergic reactions.

- heparin, which is used to thin the blood.

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

4. How do I use Rapiblyk?

How much to use

- your doctor will decide the appropriate dose for you.

If you use too much Rapiblyk

Rapiblyk will be given to you by a doctor and so it is unlikely that you will be given an overdose.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

Symptoms of an overdose may include the side effects listed in Section [6. Are there any side effects?](#) But are usually of a more severe nature.

5. What should I know while using Rapiblyk?

Things you should do

If you are about to be started on any new medicines remind your doctor or pharmacist that you have recently been given Rapiblyk.

Tell any other doctors or dentists, and pharmacists who treat you that you have been given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine.

It may affect other medicines used during the surgery.

If you plan to become pregnant, tell your doctor that you have been given this medicine. Your doctor can discuss with you the risks and benefits involved.

If you have 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 Rapiblyk may cause allergic reactions to be worse and more difficult to treat.

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

Rapiblyk may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar, called hypoglycaemia, such as fast heart beat. Rapiblyk may make low blood sugar last longer. Your doses of diabetic medicines, including insulin, may need to change.

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not drink alcohol if your doctor plans to administer Rapiblyk.

If you drink alcohol while you are being given Rapiblyk your blood pressure may drop, making you feel dizzy and faint.

Looking after your medicine

Rapiblyk will be stored by your doctor or pharmacist under the recommended conditions, out of the reach of children.

Rapiblyk should be kept in a cool dry place where the temperature stays below 25°C.

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
Skin related: <ul style="list-style-type: none"> cold sweat rash; redness of the skin Gastrointestinal related: <ul style="list-style-type: none"> nausea (feeling sick) vomiting abdominal discomfort Kidney related <ul style="list-style-type: none"> inability to pass urine Nervous system related <ul style="list-style-type: none"> headache Respiratory system related <ul style="list-style-type: none"> tightness in the chest; shortness of breath; wheezing Other: <ul style="list-style-type: none"> fever, chills injection site pain / reaction sensation of pressure yellowing of the skin and eyes; abdominal pain and swelling; swelling in the legs and ankles; itchy skin 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
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Cardiovascular related:

- low blood pressure
- slow / fast heartbeat
- feeling your heart racing or fluttering; shortness of breath; dizziness; chest pain
- fainting; feeling your heart skips a beat; fatigue

Nervous system related:

- numbness or weakness in the face, arms or legs; slurred or loss of speech; dizziness; confusion
- face drooping; vision changes; sudden, severe headache; loss of balance
- unconsciousness

Respiratory system related:

- breathing problems
- coughing; wheezing; shortness of breath; chest tightness; fatigue
- fever; chills

Kidney related:

- feeling very tired or weak; changes in urination (more or less, foamy urine); nausea
- swelling in your legs or feet; vomiting; trouble breathing; blood in urine; loss of appetite

Other:

- increased thirst; weight loss

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.

Tell your doctor 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.

7. Product details

Rapiblyk is a prescription medicine and is only administered under a doctor's supervision.

What Rapiblyk contains

Active ingredients (main ingredients)	landiolol hydrochloride
Other ingredients (inactive ingredients)	mannitol sodium hydroxide

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

What Rapiblyk looks like

Rapiblyk is a powder in the glass vial sealed with a grey rubber stopper and with a flip off tear off seal. The reconstituted solution is colourless or almost colourless.

Australian registration number :

Rapiblyk 300 mg Powder for Injection 50 mL vial
AUST R 463165

Who distributes Rapiblyk

Rapiblyk is supplied in Australia by:

Phebra Pty Ltd
19 Orion Road,
Lane Cove West,
NSW 2066, Australia.
Telephone: 1800 720 020

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