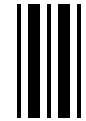




Propranolol Rosemont 50mg/5ml Oral Solution

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.



- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What is Propranolol Rosemont and what it is used for

Propranolol Rosemont 50mg/5ml Oral Solution (called Propranolol in this leaflet) contains propranolol hydrochloride. This belongs to a group of medicines called beta-blockers.

Propranolol can be used for:

- high blood pressure
- symptoms of chest pain (angina)
- protection against further heart attacks - if you have already had one
- thickened heart muscle – also called ‘hypertrophic cardiomyopathy’
- problems affecting the beat of your heart (arrhythmias, tachycardia).

It can also be used for:

- severe headaches (migraine)
- shaking (tremors)
- stress (anxiety)
- an overactive thyroid gland – also called ‘thyrotoxicosis’
- bleeding in the food pipe (oesophagus). This happens when the blood pressure is high in your liver
- high blood pressure caused by a tumour on the adrenal gland. This is called ‘phaeochromocytoma’.

2. What you need to know before you take Propranolol Rosemont

Do not take Propranolol if:

- you are allergic to propranolol or any of the other ingredients of this medicine (listed in section 6)
An allergic reaction can include a rash, itching or shortness of breath
- you have ever had asthma or wheezing
- you have heart problems such as heart failure which is not under control, heart block, slow or uneven heart beats, low blood pressure or very poor circulation
- you have not been eating (fasting) for a long period of time or if your blood has become too acidic (metabolic acidosis)
- you have high blood pressure caused by a tumour on the adrenal gland which has not been treated. This is called ‘phaeochromocytoma’
- you have or sometimes get low blood sugar (‘hypoglycaemia’). This can happen if you are not eating well, have long-term liver disease or have diabetes
- you have chest pain that happens when you are resting rather than during exercise (called ‘prinzmetals angina’).

Do not take Propranolol if any of the above apply to you. If you are not sure, talk to your doctor before taking Propranolol.

Warnings and precautions

Before you take Propranolol tell your doctor if:

- you have heart failure which is being treated

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Not known (frequency cannot be estimated from the available data)

- low levels of blood sugar (hypoglycaemia) may occur in diabetic and non diabetic patients including the newborn, toddlers and children, elderly patients, patients on artificial kidneys (haemodialysis) or patients on medication for diabetes. It may also occur in patients who are fasting or have been fasting recently or who have a long-term liver disease (signs include weakness, headache, feeling hungry, visual disturbances and mood changes).
- seizure linked to low levels of sugar in the blood.
- depression

Tell your doctor if you get any of these side effects:

Common (affects less than 1 in 10 people)

- cold fingers and toes
- numbness and spasm in the fingers which is followed by warmth and pain (Raynaud’s phenomenon)
- nightmares, tiredness or difficulty sleeping.

Uncommon (affects less than 1 in 100 people)

- feeling or being sick
- stomach ache
- diarrhoea.

Rare (affects less than 1 in 1000 people)

- feeling confused
- changes in your mood
- memory loss
- mental illness where a person loses touch with reality (psychoses)
- strange sounds and visions (hallucinations)
- thinning of the hair
- skin rash, worsening of skin problem called ‘psoriasis’
- dry eyes, changes in your sight
- tingling sensation (pins and needles) particularly in the hands.

Not known (frequency cannot be estimated from the available data)

- weight gain.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Propranolol Rosemont

- Keep out of the sight and reach of children.
- Do not store above 25°C. Do not refrigerate or freeze.
- Take back to the pharmacy 3 months after you first open it.
- Do not use after the expiry date (month, year) stated on the label and carton.
- If it is out of date or you no longer want it, take it back to the pharmacy.
- Do not use Propranolol Rosemont if you notice anything wrong with the medicine. Talk to your pharmacist.

6. Contents of the pack and other information

What Propranolol Rosemont contains

The active ingredient is propranolol hydrochloride. The other ingredients are citric acid, methyl and propyl parahydroxybenzoate (E218 and E216), propylene glycol (E1520), liquid maltitol (E965), orange/tangerine flavour (including ethanol (0.12%v/v) and butylhydroxyanisole (E320)), colouring E110 and purified water.

What Propranolol Rosemont looks like and contents of the pack

A bright orange liquid which smells of orange/tangerine. It comes in a brown glass bottle holding 150ml of solution.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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- circulation problems or other heart problems (such as angina or heart attacks) or breathlessness or swollen ankles
- you have liver problems (such as cirrhosis) or kidney problems
- you have allergic reactions to things like insect bites
- you have diabetes. This is because Propranolol may interfere with your body's reaction to low blood sugar
- you have an overactive thyroid gland – also called 'thyrotoxicosis'.

Other medicines and Propranolol

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines for diabetes
- medicines used to treat anxiety and depression as well as more serious mental health problems such as chlorpromazine, thioridazine, fluvoxamine, imipramine or MAOIs such as phenelzine and diazepam
- medicines for uneven heart beats such as disopyramide, quinidine, propafenone, lidocaine, flecainide and amiodarone
- medicines for chest pain (angina) or high blood pressure such as verapamil, nifedipine, diltiazem, nisoldipine, nicardipine, isradipine, lacidipine
- medicines used to treat high blood pressure such as hydralazine, captopril (ACE inhibitors), furosemide and other water tablets (diuretics), losartan and candesartan, diazoxide, doxazosin, guanethidine, moxislyte, moxonidine, nitrates (such as glyceryl trinitrate and isosorbide dinitrate) and methyl dopa
- medicines for stimulating the heart such as adrenaline and dobutamine
- medicines for pain and inflammation including arthritis such as ibuprofen or indomethacin
- steroids used to reduce swelling such as prednisolone and dexamethasone
- medicines used to treat myasthenia gravis such as neostigmine
- medicines used to relax muscles such as baclofen and tizanidine
- medicines to help you sleep or to treat epilepsy known as barbiturates such as phenobarbital
- medicines used to treat parkinsons disease such as levodopa
- ergotamine, dihydroergotamine and rizatriptan - used for migraine
- digoxin and warfarin - used for heart failure
- cimetidine - used for too much stomach acid
- rifampicin - used for tuberculosis
- theophylline - used for asthma
- mefloquine - used to prevent malaria
- aldesleukin - used for kidney cancer
- alprostadil - used to help men get or keep an erection or to test for erection problems
- oestrogens - used in hormone replacement therapy (HRT)
- clonidine - used for high blood pressure and migraine. You must not stop taking clonidine unless your doctor tells you to. If you have to stop taking it, your doctor will tell you how to do it.

Operations and Tests

Tell your doctor, dentist or nurse you are taking Propranolol if:

- you are going to have an operation or an anaesthetic. This is because you can get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking Propranolol
- you are going to have any blood or urine tests.

Taking Propranolol with food and drink

Do not drink alcohol while taking Propranolol. This is because alcohol can change the way the Propranolol works.

Pregnancy and Breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, planning to become pregnant or are breast-feeding.

Driving and using machines

Propranolol is not likely to affect you being able to drive or use any tools or machines. However, sometimes you may feel dizzy or tired while taking Propranolol. If this happens, do not drive or use any tools or machines and tell your doctor.

Important information about what is in Propranolol Rosemont

This medicine contains:

- Methyl and propyl parahydroxybenzoates. These may cause an allergic reaction (the allergy may happen some time after starting the medicine)
- Liquid maltitol. If your doctor has told you that you cannot tolerate some sugars, see your doctor before taking this medicine

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- A colour, sunset yellow E110. Some people are allergic to these colours
- Propylene glycol 20 mg in each ml.
- If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.
- If you are pregnant, breast-feeding, suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
 - This medicine contains 0.9 mg of alcohol (ethanol) in each ml. The amount in 5ml dose of this medicine is equivalent to less than 0.1 ml beer or 0.05 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Propranolol Rosemont

Taking this medicine

Take this medicine as your doctor or pharmacist has told you. Look on the label and ask the doctor or pharmacist if you are not sure.

- This medicine contains 50mg of propranolol in each 5ml
- Take this medicine by mouth
- Do not stop taking this medicine unless your doctor tells you to stop.

Adults

The usual doses range from 30mg - 320mg daily depending on what condition you are taking the medicine for.

Children

Your doctor will decide on the amount of Propranolol to give to your child based on their weight.

Elderly

Your doctor will decide how much Propranolol to give you. They may start you on a lower dose.

If you take more Propranolol than you should

Talk to your doctor or go to a hospital straight away.

If you forget to take Propranolol

Do not take a double dose to make up for forgotten doses. Take your next dose as soon as you remember. Then go on as before.

If you stop taking Propranolol

Keep taking this medicine until your doctor tells you to stop. You may have to stop taking this medicine gradually. Your doctor will help you do this.

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

4. Possible side effects

Like all medicines, Propranolol can cause side effects although not everybody gets them.

If you get any of the following side effects, see a doctor straight away:

- any kind of skin rash, flaking skin, boils or sore lips and mouth. You could also notice sudden wheezing, fluttering or tightness of the chest or collapse. This may mean you are having an allergic reaction to Propranolol
- if you develop asthma or breathing problems.

If you get any of the following side effects, stop taking Propranolol and see your doctor as soon as possible:

Common (affects less than 1 in 10 people)

- slow heart beats.

Rare (affects less than 1 in 1000 people)

- heart failure getting worse (signs include being breathless or swollen ankles), feeling dizzy or light-headed when standing quickly
- dizziness and fainting, worsening of breathing (called 'heart block')
- poor circulation getting worse. This can lead to cramp-like pains in the lower leg
- bruising more easily or purplish marks on the skin.

Very rare (affects less than 1 in 10,000 people)

- muscle weakness and a disease of the muscles (called 'myasthenia gravis') getting worse
- there may be changes to some of the cells or other parts of your blood. It is possible that your doctor may occasionally take blood samples to check whether Propranolol has had any effect on your blood.

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