

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **RYTHMOL**[®]

Propafenone Hydrochloride Tablets

Read this carefully before you start taking **RYTHMOL**[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **RYTHMOL**[®].

Serious Warnings and Precautions

- **RYTHMOL**[®] is intended for use only in patients with life-threatening irregular heartbeats (arrhythmias). Most anti-arrhythmic drugs have the potential to cause dangerous arrhythmias; some have been shown to be associated with an increase of sudden death. Your doctor will tell you about the risk and benefits of anti-arrhythmic therapy.

What is **RYTHMOL[®] used for?**

RYTHMOL[®] is used in adults to treat certain types of irregular heartbeats conditions known as ventricular arrhythmias.

How does **RYTHMOL[®] work?**

RYTHMOL[®] is a heart rate regulating agent. It acts on the metabolism of the heart muscles to block some of the irregular heartbeats. It also acts as a local anaesthetic, blocks the sodium current and slows down the potential of heart muscles reacting fast.

What are the ingredients in **RYTHMOL[®]?**

Medicinal ingredients: propafenone hydrochloride

Non-medicinal ingredients: croscarmellose sodium, hypromellose, macrogol 400 and 6000, magnesium stearate, microcrystalline cellulose, pregelatinized starch, purified water, and titanium dioxide.

****RYTHMOL**[®] comes in the following dosage forms:**

Film-coated tablets: 150 mg and 300 mg of propafenone hydrochloride.

Do not use **RYTHMOL[®] if:**

- you are allergic to propafenone hydrochloride or any of the other ingredients in **RYTHMOL**[®]
- you have certain severe heart conditions (e.g., Brugada Syndrome, congestive heart failure, cardiogenic shock, bradycardia, or heart conduction disorders);

- you have had a heart attack within the last 3 months;
- you have severe liver failure;
- you have lung problems (e.g., bronchospastic disorders, or severe obstructive pulmonary disease);
- you have myasthenia gravis (an autoimmune disorder that causes muscle weakness);
- you have severe hypotension (low blood pressure);
- you have severe electrolyte imbalance problems;
- you are taking ritonavir (an antiviral medication used to treat human immunodeficiency virus (HIV)).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take RYTHMOL®. Talk about any health conditions or problems you may have, including if you:

- have a family history of sudden cardiac death;
- are pregnant or plan to become pregnant;
- are breast-feeding or plan to breastfeed. RYTHMOL® is excreted into your breast milk. If you are breastfeeding, your healthcare professional will discuss alternative methods to feed your infant;
- have any heart problems;
- have abnormal blood cell counts;
- have liver problems;
- have a neuromuscular disease (e.g., myasthenia gravis);
- have kidney problems;
- have a permanent pacemaker;
- have a blockage in any part of the airway (e.g., asthma).

Other warnings you should know about:

Taking RYTHMOL® may cause the following:

- **Heart problems:** RYTHMOL® can cause other heart problems. This includes abnormal heartbeat rhythms (e.g., arrhythmias, severe ventricular tachycardia, ventricular fibrillation or torsade de pointes) and cardiac conduction reduction (problems related to the electrical system that controls your heart beat). These can be life-threatening and may require resuscitation to prevent a potentially fatal outcome. Your healthcare professional will assess your heart throughout your treatment. They may decide to reduce or stop your treatment as necessary.
- **Agranulocytosis (low level of white blood cells):** RYTHMOL® can cause agranulocytosis, usually within four to six weeks of treatment. Tell your healthcare professional if you notice or develop a fever, fatigue, discomfort, or any signs of infection. Your healthcare professional may stop your treatment with RYTHMOL®.
- **Liver problems:** RYTHMOL® can cause liver problems such as liver cell damage, increase in liver enzymes, and inflammation of the liver (hepatitis). Your healthcare professional will monitor your health and may adjust your dose of RYTHMOL®.

- **Immune problems:** RYTHMOL® can cause an abnormal blood test called Antinuclear Antibody Test or ANA Test. Your healthcare professional will monitor and assess your antinuclear antibodies (a type of antibodies produced by the immune system) at the start and during regular intervals of your treatment. They may reduce or stop your treatment.
- **Fertility problems (male):** RYTHMOL® can cause a reduction in your semen, follicle-stimulating hormone (FSH), and testosterone levels. Talk to your healthcare professional to see how RYTHMOL® can affect you.

Driving and using machines: RYTHMOL® can cause blurred vision, dizziness, fatigue, and low blood pressure. Before you drive or do tasks that require special attention, wait until you know how you respond to RYTHMOL®.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with RYTHMOL®:

- medications known as beta-blockers used to treat high blood pressure (e.g., propranolol and metoprolol);
- Quinidine, ketoconazole, and erythromycin (medications known to decrease the activity of class of enzymes (such as CYP3A4 and CYP2D6) responsible for breakdown and removal of many drugs and toxins);
- Cimetidine (used to relieve symptoms of acid reflux, heart burn and stomach ulcer by decreasing the activity of proton pump (enzyme CYP1A2));
- medications known as anticoagulants used to prevent blood clotting such as warfarin or acenocoumarol;
- certain local anesthetics (e.g., lidocaine);
- Desipramine, fluoxetine, paroxetine, fluvoxamine and venlafaxine (medications known as antidepressants used to treat depression);
- cyclosporine (used to suppress immune system function);
- theophylline (used to treat lung diseases);
- rifampin (used to treat or prevent tuberculosis and other bacterial infections);
- ritonavir and lopinavir/ritonavir products (an antiviral medication typically used to treat HIV);
- amiodarone, digoxin (used to treat or heart problems);
- phenobarbital (used to control seizures);
- St. John's Wort (herbal compound commonly used to treat depression and mood disorders);
- grapefruit juice.

How to take RYTHMOL®:

- RYTHMOL® tablets should be swallowed whole with liquid. Do not chew your tablets.
- RYTHMOL® should be taken with food.

Usual dose:

Your doctor will determine the right dose of RYTHMOL® for you. The initial adult dose of RYTHMOL® is

150 mg every 8 hours. Your doctor may decide on a different dosage depending on your situation.

Overdose:

If you think you, or a person you are caring for, have taken too much RYTHMOL[®], contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget or miss a dose, take it as soon as you remember. But if it is almost time for your next dose do not take the missed dose. Instead take the next scheduled dose. Do not try to make up for a missed dose by taking a double dose.

What are possible side effects from using RYTHMOL[®]?

These are not all the possible side effects you may have when taking RYTHMOL[®]. If you experience any side effects not listed here, tell your healthcare professional.

Some side effects include:

- gastrointestinal problems such as abdominal pain/cramping or discomfort, constipation, diarrhea, dry mouth, flatulence, loss of appetite, and unusual taste;
- nervous system problems such as anxiety, difficulty in sleeping (insomnia), and sweating;
- pain in the joints.

Check with your healthcare professional if you experience any unexpected effects, or are concerned by the above side effects.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Arrhythmia (abnormal heart rhythms): rapid, slow or irregular heartbeat		√	
Heart problems (disorders affecting your heart muscle, valves or rhythm): chest pain, chest discomfort, high blood pressure, irregular heart rhythm, shortness of breath, fainting, swelling of the legs, ankles and feet, or weakness		√	
COMMON			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Angina (not enough oxygen to the heart muscle): discomfort in the shoulder, arm, back, throat, jaw or teeth, or pain or pressure in the chest		√	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, or fatigue (may occur when you go from lying or sitting to standing up)		√	
Syncope (fainting): a temporary loss of consciousness due to a sudden drop in blood pressure		√	
Liver problems: yellowing skin or eyes, vomiting, nausea, right upper stomach area pain or swelling, unusual dark urine, or unusual tiredness		√	
Bleeding problem: excessive bruising, or easy bleeding		√	
Edema: unusual swelling of the arms, hands, legs, feet, ankles, face or airway passages		√	
UNCOMMON			
Ataxia (lack of muscle coordination): difficulty with fine motor tasks such as eating, writing or buttoning shirt, difficulty walking, loss of balance, or slurring speech		√	
UNKNOWN			
Convulsions: seizures, spasms, shaking, or fits		√	
Movement disorders: tremor, bradykinesia, muscle rigidity, restlessness, or uncontrolled movements		√	
Allergic reaction: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives, rashes, or swelling of the		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
face, lips, tongue or throat.			
Acute generalized exanthematous pustulosis (AGEP; a severe skin reaction): sudden skin eruptions, small red bumps, fever, or rashes		√	
Nervous system problems: weakness or paralysis of limbs or face, difficulty speaking, severe headache, seeing, feeling or hearing things that are not there, loss of consciousness, confusion, disorientation, or trembling		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

RYTHMOL® tablets should be stored at 15° to 25°C.

Do not take your tablets after the expiry date shown on the label.

It is important to keep the RYTHMOL® tablets in the original package.

Keep out of reach and sight of children.

If you want more information about RYTHMOL®:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this

Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.mylan.ca), or by calling 1-844-596-9526.

This leaflet was prepared by BGP Pharma ULC.

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