

PART III: CONSUMER INFORMATION

PrRYTHMOL® propafenone hydrochloride, film-coated tablets

This leaflet is PART III of a three-part "Product Monograph" published when RYTHMOL® was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about RYTHMOL®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- RYTHMOL® is used to control certain types of irregular heartbeats (arrhythmias).

What it does:

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.

When it should not be used:

Do not take RYTHMOL® if:

- you are allergic to any component of RYTHMOL®, including active ingredients and non-active ingredients;
- you have certain serious heart conditions or incidence of heart attack within the last 3 months;
- you have serious liver failure;
- you have serious lung disease;
- you have certain respiratory conditions;
- you have myasthenia gravis.
- you are younger than 18

What the medicinal ingredient is:

propafenone hydrochloride

What the non-medicinal ingredients are:

croscarmellose sodium, hypromellose, magnesium stearate, maize starch, microcrystalline cellulose, macrogol 400 and 6000, purified water, titanium dioxide

What dosage forms it comes in:

RYTHMOL® is available as film-coated tablets in the following strengths: 150 mg and 300 mg.

WARNINGS AND PRECAUTIONS

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.

BEFORE you use RYTHMOL® talk to your doctor or pharmacist if:

- you have a family history of sudden cardiac death or suffer from Brugada Syndrome;
- you are pregnant or planning to become pregnant, or you are breast-feeding;
- you have any heart disease;
- you have abnormal blood cell counts;
- you have abnormal liver function;
- you have neuromuscular disease (e.g. myasthenia gravis);
- you have kidney disease;
- you have allergies to this drug or any of its ingredients.
- you perform tasks which require special attention (for example, driving automobile or operating dangerous machinery) because blurred vision, dizziness, fatigue and low blood pressure are common side effects associated with the administration of RYTHMOL®.

INTERACTIONS WITH THIS MEDICATION

The following may interact with RYTHMOL®:

- beta-blockers (e.g. propranolol, metoprolol);
- digoxin, venlafaxine, rifampin, cimetidine, quinidine, ketoconazole, erythromycin, amiodarone, phenobarbital;
- anticoagulants (e.g. warfarin);
- certain local anesthetics (e.g. lidocaine);
- certain antidepressants of the tricyclic group (e.g. desipramine), and other antidepressants (e.g. fluoxetine, paroxetine, fluvoxamine);
- some medication that can affect your immune system (e.g. cyclosporine);
- some HIV-antiviral medication (e.g. ritonavir, lopinavir/ritonavir);
- grapefruit juice.

PROPER USE OF THIS MEDICATION

Usual dose:

Dosage must be individualized. The usual adult dose of RYTHMOL® is 150 mg which is to be taken every 8 hours, however your doctor may decide on different individual dosing.

The film-coated tablets should be swallowed whole (without chewing) with liquid. Recommended to be taken with food.

Overdose:

If you or someone you know accidentally takes more than stated dose, contact your doctor or Regional Poison Control Centre immediately or go to the nearest hospital with the tablets. Tell your doctor or hospital how much was taken. Treat even small overdoses seriously.

Missed Dose:

If you forget to take one tablet, take another as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed tablet at all.

Never double-up on a missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its needed effects, a medicine may cause some unwanted effects. These are referred to as “side effects”. Although not all of these side effects may occur, if they do occur they may need medical attention.

The most common side effects with RYTHMOL® are dizziness, feeling sick (nausea), vomiting, unusual taste, and constipation. Other less common side effects may include headaches, blurred vision, difficulty in sleeping, tremor, drowsiness, dyspepsia, dry mouth, loss of appetite, abdominal pain/cramping, flatulence, tiredness, skin rash, weakness, chest pain, anxiety, severe sweating and pain in the joints.

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist as soon as possible	
	Only if severe	In all cases		
Very common	Fast heartbeat, irregular heartbeats		√	
Common	chest pain,		√	
	dizziness, lightheadedness, fainting		√	
	liver problems (e.g., yellowing skin or eyes, prolonged vomiting and nausea or abdominal pain)		√	
	bleeding problem (excessive bruising, easy bleeding)		√	
Not common	Abnormal muscular control (ataxia)		√	
Unknown	Heart rate reduced		√	
	Convulsion, movement disorders (extrapyramidal symptoms), restlessness		√	

This is not a complete list of side effects. For any unexpected effects while taking RYTHMOL®, contact your doctor or pharmacist.

STORAGE

Keep RYTHMOL® and all other medicines out of reach and sight of children.

RYTHMOL® tablets should be stored at 15° to 25°C, protected from light and moisture.

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.

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 (<http://www.hc-sc.gc.ca/dhpmps/medeff/report-declaration/index-eng.php>) 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.

MORE INFORMATION

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 (<http://hc-sc.gc.ca/index-eng.php>); 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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