NEW ZEALAND CONSUMER MEDICINE INFORMATION

RYTMONORM®
Propafenone Tablets 150 mg & 300 mg

What is in this leaflet

This leaflet answers some common questions about RYTMONORM. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking RYTMONORM against the benefits they expect it will have for you.

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

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

What RYTMONORM is used for

RYTMONORM contains the active ingredient propafenone hydrochloride. RYTMONORM belongs to a group of medicines called anti-arrhythmic agents.

Rytmonorm slows down the heart rate and helps to regulate the heartbeat. Rytmonorm tablets are used to treat and prevent arrhythmias (abnormal heart rhythms) anti-arrhythmic drug.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor’s prescription.

There is not enough information to recommend the use of this medicine for children.

Before you take RYTMONORM

When you must not take it

Do not take RYTMONORM if you have an allergy to:

- any medicine containing propafenone hydrochloride
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take RYTMONORM if you:

- have a heart condition called Brugada Syndrome
- have significant heart disease such as heart failure or any heart problems other than abnormal heart rhythm
- have severe symptomatic slow heart beat
- have changes in heart rate in the absence of an artificial pacemaker
- have severe low blood pressure
- have difficulty in breathing, such as asthma or chronic bronchitis or emphysema
- manifest electrolyte imbalance (e.g. potassium metabolism disorders)
- have severe lung disease
- have a condition known as myasthenia gravis (disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs)
- are concomitantly taking ritonavir and propafenone hydrochloride.

Do not give this medicine to children. Safety and effectiveness in children have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

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 have allergies to any other medicines, foods, preservatives or dyes.

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

- a heart condition called Brugada Syndrome
- change in heart rate
- difficulty of breathing that is not due to an allergy
- heart failure
- heart rhythm problems
- have a pacemaker
- disturbances in the salts in your body
- liver problems
- kidney problems
- autoimmune disorders.

Tell your doctor or pharmacist if you are pregnant, intend to become pregnant or are breastfeeding. Your doctor or pharmacist can discuss the risks and benefits of taking RYTMONORM when pregnant or whilst breastfeeding.
If you have not told your doctor about any of the above, tell him/her before you start taking RYTMONORM.

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

Some medicines and RYTMONORM may interfere with each other. These include:

- medicines that affect the activity of the heart (e.g. amiodarone, digoxin, quinidine)
- medicine used to prevent blood clots (e.g. warfarin)
- antibiotics used to treat infections (e.g. erythromycin or rifampicin)
- any of the group of medicines known as beta-blockers, used to treat high blood pressure (e.g. propranolol, metoprolol)
- any antiviral agents (e.g. ritonavir)
- any of the group of medicines know as a tranquillisers, or an antidepressant of the tricyclic or related group (e.g. desipramine)
- medicines used to treat depression (e.g. venlafaxine, fluoxetine, paroxetine)
- medicine used to treat reflux and ulcers (e.g. cimetidine)
- medicine used after transplant operations, or in the treatment of arthritis or psoriasis (e.g. ciclosporin)
- medicines used to treatment asthma (e.g. theophylline)
- medicines used to treat fungal infections (e.g. ketoconazole)
- medicines used to treat epilepsy (e.g. phenobarbital)
- grapefruit juice as it may interfere with the way this medicine works in your body.

These medicines may be affected by RYTMONORM or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take RYTMONORM
Follow all directions given to you by your doctor or pharmacist carefully.
They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take
Follow your doctor’s directions about when and how to take your tablets and look at the label on the carton. Your pharmacist will also help if you are not sure. The number of tablets that you will need to take will be decided by your doctor.

This may be:
- 1 film-coated tablet of Rytmonorm 150 mg 3 times a day,
- up to 1 film coated tablet of Rytmonorm 300 mg three times a day.

You may need a lower dose of Rytmonorm if you are elderly, if you have problems with your kidneys or liver, or if you have a low bodyweight.

How to take it
Swallow the tablets whole, without chewing them with a full glass of water after meals. Do not take with grapefruit juice.

When to take it
Take your medicine at about the same time each day.
Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it
Continue taking your medicine for as long as your doctor tells you.
This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it
If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.
Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.
This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.
If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)
Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much RYTMONORM. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The symptoms of overdose, which are usually most severe within 3 hours of ingestion, may include:

- low blood pressure
- somnolence
- irregular heart beat.
While you are taking RYTMONORM

**Things you must do**

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

**Things you must not do**

Do not take RYTMONORM to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

**Things to be careful of**

Be careful driving or operating machinery until you know how RYTMONORM affects you. This medicine may cause blurred vision, dizziness, tiredness and low blood pressure in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

This medicine helps most people with irregular heartbeats, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- unusual taste
- dizziness
- headache
- constipation
- nausea and/or vomiting
- heart palpitations (being aware of your heart beat)
- blurred vision
- dry mouth
- shortness of breath
- anxiety.

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- a rash, itching or skin reddening or other signs of an allergic reaction such as difficulty breathing. Although these are rare, they can be serious.
- yellowing of the skin and/or eyes, as these may be a sign of liver problems
- you start to bruise easily or if you develop a very sore throat with a high fever, as in very rare cases, treatment may affect the amount of white blood cells and platelets in the blood.

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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

A reversible drop in sperm count has occasionally been reported with high doses.

After taking RYTMONORM

**Storage**

Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store RYTMONORM or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it 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.

**Disposal**

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

**Product description**

**What it looks like**

Rytmonorm 150 mg

White to off-white, round, biconvex film coated tablets embossed on one face with “150”, with the “Knoll triangle” below. The other face is unmarked.
Rytmonorm 300 mg *

White to off-white round, biconvex, film-coated tablets embossed on one face with “300” above a scoreline, and the “Knoll Triangle” below. The other face is scored.

* Not currently marketed in New Zealand

**Ingredients**

RYTONORM tablets contain either 150 mg or 300 mg of propafenone hydrochloride as the active ingredient.

It also contains:

- microcrystalline cellulose
- maize starch
- hypromellose
- croscarmellose sodium
- purified water
- macrogol
- titanium dioxide (E171)
- magnesium stearate.

This medicine does not contain lactose and gluten.

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**If you want to know more**

Should you have any questions regarding this product, please contact your pharmacist or doctor.

**Who supplies this medicine**

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792.

**Date of Information**

4 August 2017
(Based on datasheet dated 15 June 2017)