

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Rythmodan. 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 or pharmacist has weighed the risks of you taking Rythmodan 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 Rythmodan is used for

Rythmodan belongs to a group of medications called antiarrhythmics. This means it acts to correct irregular heartbeats to a normal rhythm and to slow an overactive heart. This allows the heart to work more efficiently.

Rythmodan is used to treat and prevent ventricular arrhythmias (irregular heartbeat).

**Ask your doctor if you have any questions about why Rythmodan has been prescribed for you.**

Your doctor may have prescribed Rythmodan for another reason. This medicine is available only with a doctor's prescription.

### Before you take Rythmodan

#### *When you must not take it*

**Do not take Rythmodan if you have an allergy to Rythmodan or any of the ingredients listed at the end of this leaflet.**

Some symptoms of an allergic reaction may include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not give Rythmodan to a child or adolescent. Rythmodan is not recommended for use during pregnancy, unless you and your doctor or pharmacist have discussed the risks and benefits involved.

Do not take Rythmodan if you are taking other antiarrhythmics or other heart medications without first discussing with your doctor.

Do not take Rythmodan without first discussing all previous and preexisting heart problems with your doctor.

**Do not take Rythmodan if you are breast-feeding or plan to breast-feed.**

Rythmodan passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Rythmodan is not recommended for use in children.

**Do not take Rythmodan after the expiry date (EXP) printed on the pack.**

If you take this medicine after the expiry date has passed, it may not work as well.

**Do not take Rythmodan 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 Rythmodan, contact your doctor or pharmacist.**

#### *Before you start to take it*

**Tell your doctor or pharmacist if you have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes

**Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.**

Your doctor or pharmacist will discuss the possible risks and benefits of using Rythmodan during pregnancy.

**Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.**

Rythmodan is not recommended while you are breast-feeding.

**Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:**

- Diabetes
- Glaucoma or a family history of glaucoma
- Chronic muscular weakness (Myasthenia Gravis)
- Kidney problems
- Liver problems
- Heart problems including heart failure, heart attack, chest pain
- Low blood pressure (dizziness or light-headedness)
- Low or high potassium levels in your blood
- Bowel problems
- Difficult urination or
- Enlarged prostate

#### *Taking other medicines*

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

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

- Other antiarrhythmics used to treat heart conditions such as beta-blockers, amiodarone and calcium channel blockers
- Diuretics or antiangina medication
- Medicines used to treat epilepsy or fits, especially phenytoin and phenobarbitone
- Tricyclic and tetracyclic antidepressants
- Antibacterials to treat infections such as rifampicin, erythromycin, roxithromycin and clarithromycin
- Antifungals such as fluconazole, ketoconazole, itraconazole and amphotericin B
- Antimicrobials to treat infections, such as pentamidine
- Medications used to treat HIV
- Antihistamines such as terfenadine and astemizole
- Cisapride, a medicine used to treat stomach problems
- Pimozide, a medicine used to treat certain mental illnesses
- Laxatives for constipation
- Medicines for erectile dysfunction such as Viagra or Levitra

- Warfarin, a medicine used to prevent blood clots

These medicines may be affected by Rythmodan, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

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

### How to take it

#### *How much to take*

The dose of Rythmodan may be different for each person. Your doctor will decide the right dose for you.

#### *How to take it*

Swallow Rythmodan whole with plenty of fluid.

The daily dose of Rythmodan is usually taken in three equally divided doses.

#### *When to take it*

**Take Rythmodan at about the same time each day.**

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

It does not matter if you take Rythmodan before or after food.

This medicine works best when there is a constant amount in the blood. To help keep the amount constant it is best to take the doses at evenly spaced intervals day and night.

#### *How long to take it*

Rythmodan helps control your condition, but does not cure it. Therefore you must take Rythmodan every day. Continue taking the capsules for as long as your doctor or pharmacist tells you.

Do not stop taking your capsules because you are feeling better.

#### *If you forget to take it*

**If it is almost time for your next dose (within 4 hours), 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 try to make up for a missed dose by taking more than one dose at a time.** 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 pharmacist or the Poisons Information Centre (telephone 13 11 26 and in New Zealand telephone 0800 764766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Rythmodan. Do this**

**even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take too much Rythmodan, you may feel cold and dizzy, light-headed, weak or you may faint. You may also experience palpitations (your heart may feel like it "skips a beat") and have difficulty breathing. You may notice your pulse is rapid and weak.

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#### While you are taking it

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##### *Things you must do*

**Tell all the doctors, dentists, and pharmacists who are treating you that you are taking Rythmodan.**

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Rythmodan.**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Rythmodan.**

**Rythmodan may cause hypoglycaemia (low blood sugar) in some people.**

Patients with congestive heart disease or diabetes should be aware of the signs (see side effects) and if the signs appear eat or drink a food containing sugar and call your doctor.

Rythmodan may cause dryness of the mouth, nose and throat.

For temporary relief of mouth dryness melt bits of ice in your mouth. However, if dryness continues for more than 2 weeks, check with your medical doctor or dentist.

**If you become pregnant while taking Rythmodan, tell your doctor or pharmacist.**

##### *Things you must not do*

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

**Do not take Rythmodan to treat any other complaints unless your doctor or pharmacist tells you to.**

**Do not stop taking Rythmodan, or lower the dosage, without checking with your doctor or pharmacist.**

##### *Things to be careful of*

**Be careful driving or operating machinery until you know how Rythmodan affects you.**

It may cause dizziness, light-headedness or fainting in some people. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

**The effects of alcohol could be made worse while taking Rythmodan. It is not recommended that you drink alcohol while taking Rythmodan.**

Alcohol may make the low blood sugar (hypoglycaemia) effect worse and/or increase the possibility of dizziness or fainting.

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#### Side effects

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All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using

this medicine against the benefits they expect it will have for you.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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

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

- Dry mouth, eyes, nose or throat
- Bloating or stomach pain
- Blurred vision
- Constipation or diarrhoea
- Drowsiness
- Frequent urge to urinate
- Loss of appetite
- Nausea and vomiting
- Increased perspiration
- Increased skin sensitivity to light

These are mild side effects of this medicine and usually short-lived.

**Tell your doctor or pharmacist as soon as possible if you notice any of the following:**

- Difficult urination
- Redness, itching, swelling, blistering, itchy or raised skin rash, and/or hives
- Chest pains
- Dizziness, light-headedness or fainting
- Fast or irregular heartbeat
- Muscle weakness
- Shortness of breath
- Swelling of feet or lower legs
- Frequent infections such as sore throat or fever
- Yellowing of the skin and/or eyes
- Hypoglycaemia (low blood sugar). The signs and symptoms of hypoglycaemia are: chills, cold sweats, confusion, cool and pale skin, drowsiness, headache, fast heartbeat, excessive hunger, nausea, shakiness, unusual tiredness/weakness.

These may be serious side effects of Rythmodan. You may need urgent medical attention.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

Other side effects not listed above may occur in some patients.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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

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#### After taking it

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**If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.**

##### *Storage*

**Keep your capsules in the pack until it is time to take them.**

**Keep your capsules in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink.**

**Do not leave it in a car or on a windowsill.**

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 or pharmacist tells you to stop taking Rythmodan or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.**

**Return any unused medicine to your pharmacist.**

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#### Product description

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##### *What it looks like*

Rythmodan 100mg capsules are green and beige, marked with RY on one part and RL on the other.

Rythmodan 150mg capsules<sup>#</sup> are white, marked with RY on one part and 150 on the other.

Rythmodan is available in blister packs of 100 capsules.

##### *Ingredients*

Rythmodan capsules contain either 100mg or 150mg of disopyramide, as the active ingredient. Each capsule also contains: magnesium stearate, maize starch, purified talc, gelatin, titanium dioxide. The 100mg capsules also contain yellow iron oxide and indigo carmine.

Rythmodan does not contain lactose, sucrose, gluten, tartrazine or azo-dyes.

##### *Sponsor*

Rythmodan is supplied in Australia by:  
sanofi-aventis australia Pty Ltd  
12-24 Talavera Road  
Macquarie Park  
NSW 2113  
Australia

Rythmodan is supplied in New Zealand by:  
sanofi-aventis new zealand limited  
Level 8, 56 Cawley Street  
Ellerslie, Auckland  
New Zealand

Australian Registration Numbers:

100mg capsules: AUST R 13537

150mg capsules#: AUST R 13538

New Zealand Registration Numbers:

100mg capsules: TT50-2101

150mg capsules#: TT50-2101a

Date of preparation: August 2017

<sup>#</sup>Not marketed

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