

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Rythmodan Retard® 250mg Prolonged Release Tablets disopyramide

SANOFI



**Is this leaflet hard to see  
or read?**

**Phone 014035 600 for help**

**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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **What is in this leaflet:**

- 1. What Rythmodan Retard is and what it is used for
- 2. Before you take Rythmodan Retard
- 3. How to take Rythmodan Retard
- 4. Possible side effects
- 5. How to store Rythmodan Retard
- 6. Further information

#### **1. What Rythmodan Retard is and what it is used for**



The name of your medicine is Rythmodan Retard 250mg Prolonged Release Tablets (called Rythmodan Retard in this leaflet). Rythmodan Retard contains a medicine called disopyramide. This belongs to a group of medicines called anti-arrhythmic agents. It works by controlling the uneven beating of your heart and returns it to the normal rhythm.

#### **It is used for controlling your heartbeat in the following situations:**

- Arrhythmias - where your heartbeats are uneven, or unusually fast or slow
- To keep your heart beating at a normal rhythm
- To stop unusual heartbeats (arrhythmias) happening after a heart attack
- To stop unusual heartbeats (arrhythmias) during an operation



#### **2. What you need to know before you take Rythmodan Retard**

#### **Do not take Rythmodan Retard if:**

- You are allergic (hypersensitive) to disopyramide or any of the other ingredients of Rythmodan Retard (see Section 6: Further Information). Signs

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of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

- You have any other heart problems - apart from unusual heartbeats (arrhythmias)
- You are taking other medicines to control your heart rhythm (see section below 'Taking other medicines')
- You are taking other medicines which could cause unusual heartbeats (see section below 'Taking other medicines')
- You have any kidney or liver problems

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Rythmodan Retard.



#### **Warnings and precautions**

##### **Take special care with**



##### **Rythmodan Retard**

**Check with your doctor or pharmacist  
before taking your  
medicine if:**

- You have low levels of potassium in your blood (called hypokalaemia)
- You have low blood sugar levels. This can happen if you have diabetes, a low body weight, a poor diet or if you are elderly
- you have glaucoma (an eye condition often caused by an



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créé le par modifié le par	<b>25/08/2016</b> <b>E Wasczcyk</b> <b>28/10/2016</b> <b>Thill G</b>	Nom du produit Référence article Dosage Quantité	<b>Rythmodan</b> <b>R778530</b> <b>250 mg</b> <b>cps</b>				Code sécurité <b>778530</b>
Laboratoires Pays	<b>Sanofi</b> <b>Irlande</b>	Couleur Nbre/Réf.	<b>1</b>	<b>Bleu Reflex Blue U</b>			Numéro de pages <b>1/4</b>

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- abnormally high pressure in the eye, that damages the optic nerve and can lead to blindness); in this case you should not use Rythmodan.
- you have ever had glaucoma in your life or if someone in your family has ever had glaucoma: in this case your doctor will perform an eye pressure test before prescribing Rythmodan.
  - You have an enlarged prostate
  - You have a disease which causes muscle weakness (myasthenia gravis)
  - Impairment of memory, thinking, attention or understanding.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Rythmodan Retard.

#### **Other medicines and Rythmodan Retard**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Rythmodan Retard can affect the way some other medicines work. Also some medicines can affect the way Rythmodan Retard works.

**In particular, do not take this medicine and tell your doctor:**

#### **If you are taking any of the following medicines for uneven heartbeats (arrhythmias):**

- Beta-blockers such as propranolol, oxprenolol or acebutolol
- Verapamil - used for chest pain or high blood pressure
- Digoxin - used for heart problems


#### **If you are taking any of the following medicines that can increase the risk of unusual heartbeats (arrhythmias) when taken at the same time as Rythmodan Retard:**

- Medicines for depression such as amitriptyline, imipramine or maprotiline
- Medicines for male sexual problems such as sildenafil, tadalafil or vardenafil
- Antibiotics such as erythromycin, clarithromycin, azithromycin or sparfloxacin
- Antihistamines such as astemizole or terfenadine
- Cisapride - used for heartburn
- Pentamidine - used for pneumonia
- Pimozide and thioridazine - used for schizophrenia

#### **The following medicines may affect the way Rythmodan Retard works:**

- Amphotericin B - used for fungal infections

- Tetracosactide - used to test some hormone problems
  - Rifampicin - used for infections
  - Atropine - used in eye drops and in cough and cold medicines
  - Anticholinergic medicines - includes some medicines used for irritable bowel syndrome, asthma or incontinence
- It is possible that a blockage of your bowel may occur due to a paralysis of your intestinal muscles, especially if you are elderly, and when Rythmodan is taken with other medicines that may cause constipation or in situations where the blood level of Rythmodan is increased (e.g. Kidney or liver problems or if you take too much of Rythmodan).
- Medicines used to calm emotional or mental problems or stop you feeling sick or being sick such as chlorpromazine or prochlorperazine
  - Water tablets (diuretics) such as furosemide
  - Corticosteroids, such as hydrocortisone, betamethasone or prednisolone
  - Laxatives such as bisacodyl or senna
  - Medicines for epilepsy such as phenobarbital, primidone or phenytoin
- Rythmodan Retard may affect the way the following medicines work:**
- Medicines for HIV infections such as ritonavir, indinavir or saquinavir

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- Theophylline - used for wheezing or difficulty in breathing
- Ciclosporin - used to help prevent rejection of transplants
- Warfarin - used to thin the blood

#### **Pregnancy, breast-feeding and fertility**

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine. This is because small amounts of this medicine may pass into the mothers' milk.

#### **Driving and using machines**

Rythmodan Retard may affect your ability to concentrate and react quickly.

You may have blurred vision or become dizzy or light-headed. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Rythmodan Retard:

Contains anhydrous glucose and sucrose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. How to take Rythmodan Retard**

Always take Rythmodan Retard exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

#### **Taking this medicine**

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

#### **Adults**

The usual starting dose is one tablet twice a day.

#### **Use in children**

Rythmodan Retard is not suitable for use in children.

#### **Blood tests**

Your doctor may ask you to have regular blood tests to check your blood sugar levels.

#### **If you take more Rythmodan Retard than you should**

If you take more tablets than you should, talk to a doctor or go to a hospital casualty department straight away. Take the medicine pack with you.

This is so the doctor knows what you have taken. The following effects may happen: dizziness, feeling tired, uneven heartbeat (palpitations), dry mouth, difficulty in passing water (urinating), feeling or being sick, blockage of the bowel, stomach pain or fits (seizures).

#### **If you forget to take Rythmodan Retard**

Do not take a double dose to make up for a forgotten tablet.

#### **If you stop taking Rythmodan Retard**

Keep taking Rythmodan Retard until your doctor tells you to stop.

If you have any further questions about this medicine, ask your doctor or pharmacist.



### **4. Possible side effects**

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

#### **Tell your doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment**

- If you have an allergic reaction. The signs may include: a skin rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue





**Tell your doctor as soon as possible if you have any of the following side effects:**

- Feeling faint, dizzy or light-headed
- Palpitations or an uneven, fast or slow heartbeat that you have not had before or that gets worse

**Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet:**

- Feeling sick (nausea) or being sick (vomiting), dry mouth, indigestion, diarrhoea, constipation, stomach pain, loss of appetite
- Difficulty in passing urine
- Difficulty in getting or maintaining an erection, or in ejaculating (impotence)
- Mood changes or mental problems
- Blurred or double vision
- Yellowing of your skin or eyes (jaundice)
- Worsening of myasthenia gravis (a disease which causes muscle weakness)
- deficiency in white blood cells called «granulocytes»
- You may get more infections than usual. This could be caused by a lowering in the number of white blood cells (called neutropenia)
- Low blood sugar levels (hypoglycaemia). Signs include sweating, paleness, headache, feeling faint or drowsy

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects and not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Rythmodan Retard**

Keep out of the reach and sight of children. Do not use Rythmodan Retard after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not use Rythmodan Retard if you notice your tablets are crumbling, broken or discoloured.

Do not store above 25°C. Store in the original package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Contents of the pack and other Information**

**What Rythmodan Retard contains**

- Each tablet contains 250mg of the active substance, disopyramide base.

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- The other ingredients are glyceryl monostearate, sucrose, povidone and magnesium stearate, hypromellose, propylene glycol, anhydrous glucose.

**What Rythmodan Retard looks like**

and contents of the pack  
The tablets are biconvex and whitish in colour. One side has a break-line and is embossed 013 and E. The other side is embossed with the Roussel Uclaf logo. The tablets are available in blister-packs of 60 tablets.

**Marketing Authorisation Holder and**

**Manufacturer**

Marketing Authorisation Holder  
Sanofi-aventis Ireland Ltd., T/A SANOFI  
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Republic of Ireland.  
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email: [Imedinfo@sanofi.com](mailto:Imedinfo@sanofi.com)

**Manufacturer**

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56 Route de Choisy-au-Bac  
60205 Compiègne - France

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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