

Rythmodan Retard®
250 mg Modified Release Tablets
(disopyramide phosphate)

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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Rythmodan Retard is and what it is used for
2. What you need to know before you take Rythmodan Retard
3. How to take Rythmodan Retard
4. Possible side effects
5. How to store Rythmodan Retard
6. Contents of the pack and other information

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

The name of your medicine is Rythmodan Retard 250 mg Modified 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 to disopyramide or any of the other ingredients of this medicine (listed in section 6).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- if you have any other heart problems, - apart from unusual heartbeats (arrhythmias).
- if you are taking other medicines to control your heart rhythm (see section below 'Other medicines and Rythmodan Retard').
- if you are taking other medicines which could cause unusual heartbeats (see section below 'Other medicines and Rythmodan Retard').
- if 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

Talk to your doctor or pharmacist before taking Rythmodan Retard:

- if you have low levels of potassium in your blood (called hypokalaemia).
- if 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.
- if you have glaucoma (an eye condition often caused by an abnormally high pressure in the eye) or if you or someone in your family have ever had glaucoma. Your doctor may perform an eye pressure test before prescribing Rythmodan Retard.
- if you have an enlarged prostate.
- if you have a disease which causes muscle weakness (myasthenia gravis).
- if you are elderly and have problems with your memory or attention span, or sometimes have difficulty thinking clearly.
- if you have constipation or take any medication that causes constipation.

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 – also 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
- 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
- Theophylline - used for wheezing or difficulty in breathing
- Ciclosporin - used to help prevent rejection of transplants
- Warfarin - used to thin the blood

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are breast-feeding or planning to breast-feed, ask your doctor or pharmacist for advice before taking this 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.

Rythmodan Retard contains sucrose and glucose

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 this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets with a drink of water
- Do not break, crush or chew your tablets
- 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 to one and a half tablets (250mg to 375mg) twice a day.

Elderly

Your doctor may lower your dose if you have any kidney or liver problems.

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, 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 on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine 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, especially in men with prostate problems
- 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)
- You 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.
- Problems with memory or attention span, difficulty thinking clearly
- In certain situations the bowel may become blocked, especially in the elderly, when Rythmodan Retard is taken with other medicines that may cause constipation or when blood levels of disopyramide are raised due to kidney or liver problems.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

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 sight and reach 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.

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 disopyramide (as phosphate).

The other ingredients are glyceryl monostearate, glucose, sucrose, povidone E1201 and magnesium stearate (E470b).

The film coating contains hypromellose E464, propylene glycol E1520 and glucose.

What Rythmodan Retard look like and contents of the pack

The tablets are biconvex and white in colour. One side has a break-line and is embossed 013 and E. The other side is embossed with the Roussel logo.

The tablets are available in blister-packs of 60 tablets.

Manufacturers:

Sanofi Winthrop Industrie
56, route de Choisy-au-Bac
60205 Compiègne, France.

Opella Healthcare International SAS
56, Route de Choisy, 60200 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.

Procured within the EU.

Product licence Holder: Ecosse Pharmaceuticals Limited
3 Young Place, East Kilbride G75 0TD.

Re-packager: Munro Wholesale Medical Supplies Limited
3 Young Place, East Kilbride G75 0TD.

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If you are blind or partially sighted and require this leaflet in a different format, call 01355 574450 and ask for the Regulatory Department.

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