

Rythmodan® 100mg Capsules Disopyramide 100mg Capsules

(disopyramide)

0125
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PATIENT INFORMATION LEAFLET

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 Capsules are and what they are used for
2. What you need to know before you take Rythmodan Capsules
3. How to take Rythmodan Capsules
4. Possible side effects
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1. WHAT RYTHMODAN CAPSULES ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Rythmodan 100mg Capsules / Disopyramide 100mg Capsules (called Rythmodan Capsules in this leaflet). Rythmodan Capsules contain a medicine called disopyramide.

This belongs to a group of medicines called antiarrhythmic 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 CAPSULES

Do not take Rythmodan Capsules:

- 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 Capsules').
- if you are taking other medicines which could cause unusual heartbeats (see section below 'Other medicines and Rythmodan Capsules').

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 Capsules.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rythmodan Capsules:

- 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 Capsules.
- if you have an enlarged prostate.
- if you have any kidney or liver problems.
- 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 Capsules.

Other medicines and Rythmodan Capsules

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 Capsules can affect the way some other medicines work. Also, some medicines can affect the way Rythmodan Capsules work.

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 – also 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 Capsules:

- 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 sparfloracin
- 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 Capsules work:

- 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 Capsules 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 Capsules 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.

3. HOW TO TAKE RYTHMODAN CAPSULES

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 capsules 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 three to eight capsules (300 to 800 mg) in divided doses daily.

Elderly

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

Children

Rythmodan Capsules are 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 Capsules than you should

If you take more capsules 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 Capsules

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

If you stop taking Rythmodan Capsules

Keep taking Rythmodan Capsules 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:

Not known (frequency cannot be estimated from available data)

- 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.

Other side effects:

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

Not known (frequency cannot be estimated from available data)

- 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:

Rare (may affect up to 1 in 1,000 patients)

- Low blood sugar levels (hypoglycaemia). Signs include sweating, paleness, headache, feeling faint or drowsy.

Very rare (may affect up to 1 in 10,000 patients)

- Yellowing of your skin or eyes (jaundice)
- You get more infections than usual. This could be caused by a lowering in the number of white blood cells (called neutropenia).
- Rashes
- Headache

Not known (frequency cannot be estimated from the available data)

- A lack of white blood cells called agranulocytosis, which may cause sudden high fever, severe sore throat and mouth ulcers.
- 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
- Increased eye pressure in patients with glaucoma
- Blurred or double vision
- Worsening of myasthenia gravis (a disease which causes muscle weakness)
- Problems with memory or attention span, difficulty thinking clearly
- In certain situations, the bowel may become blocked, especially in the elderly, when Disopyramide Tablets are 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 Yellow Card Scheme Website:

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 CAPSULES

- Keep out of the sight and reach of children.
- Do not store above 25°C. Protect from light.
- Do not use Rythmodan Capsules 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 Capsules if you notice your capsules are crumbling, broken or discoloured.
- 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 Capsules contain

Each capsule contains 100mg of the active ingredient disopyramide. The other ingredients are maize starch, lactose, magnesium stearate, talc, gelatin, indigo carmine (E132), iron oxide, and titanium dioxide (E171)

What Rythmodan Capsules look like and contents of the pack

Rythmodan Capsules are yellow and green capsules and are available in blister packs of 90, 100 and 120 capsules.

Manufacturer and product licence holder

Manufactured by:

- Opella Haelthcare International SAS, 56 Route de Choisy, F-60200 Compiègne, France.
- Erfa NV, Landbouwersstraat 25, B-1040, Brussels, Belgium.

Procured from within the EU. Repackaged by the product licence holder P.I.E. Pharma Ltd, 207 Kenton Road, Harrow, Middlesex HA3 0HD.

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