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2. Rythmol SR

# **Rythmol SR (Oral)**

Generic name: propafenone [ proe-PA-fen-one-hye-droe-KLOR-ide ]

**Brand names:** Rythmol, Rythmol SR **Drug class:** Group I antiarrhythmics

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Uses Before taking Dosage Warnings Side effects Brand names

Oral route(Tablet; Capsule, Extended Release)

It is prudent to consider any Class 1C antiarrhythmic to have a significant proarrhythmic risk in patients with structural heart disease. Given the lack of any evidence that these drugs improve survival, antiarrhythmic agents should generally be avoided in patients with non-life-threatening ventricular arrhythmias, even if the patients are experiencing unpleasant, but not life-threatening, symptoms or signs.

## **Uses for Rythmol SR**

Propafenone is used to prevent irregular heartbeats such as atrial fibrillation (AF) from occurring again in patients who do not have structural heart disease.

Propafenone belongs to the group of medicines known as antiarrhythmics. It works directly on the heart tissue and will slow the nerve impulses in the heart. This helps keep the heart rhythm normal.

There is a chance that propafenone may cause new or make worse existing heart rhythm problems when it is used. Since it has been shown to cause severe problems in some patients, propafenone is only used to treat serious heart rhythm problems. Discuss this possible effect with your doctor.

This medicine is available only with your doctor's prescription.

## Before using Rythmol SR

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

## **Allergies**

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

### **Pediatric**

Appropriate studies have not been performed on the relationship of age to the effects of propafenone in the pediatric population. Safety and efficacy have not been established.

#### **Geriatric**

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of propafenone in the elderly.

## **Breast Feeding**

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

## Interactions with Medicines

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.

- Bepridil
- Cisapride
- Dronedarone
- Fluconazole
- Ketoconazole
- Levoketoconazole
- Levomethadyl
- Mesoridazine
- Nelfinavir
- Nirmatrelvir
- Pimozide
- Piperaquine
- Posaconazole
- Ritonavir
- Saquinavir
- Sparfloxacin
- Terfenadine

Tipranavir Vernakalant • Ziprasidone Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines. Abiraterone Acetate Acecainide Adagrasib • Ajmaline • Alfuzosin • Amiodarone • Amisulpride • Amitriptyline Amoxapine Anagrelide • Apomorphine • Aprindine • Aripiprazole • Aripiprazole Lauroxil Arsenic Trioxide Artemether • Asenapine Astemizole Atazanavir Azimilide • Azithromycin • Boceprevir Bretylium • Buprenorphine • Bupropion Buserelin

• Thioridazine

Ceritinib

- Chloral HydrateChloroquineChlorpromazineCiprofloxacinCitalopram
  - Clarithromycin
  - Clofazimine
  - Clomipramine
  - Clothiapine
- Clozapine
- Cobicistat
- Crizotinib
- Dabrafenib
- Darunavir
- Dasabuvir
- Dasatinib
- Degarelix
- Delamanid
- Delavirdine
- Desipramine
- Deslorelin
- Desvenlafaxine
- Deutetrabenazine
- Dexmedetomidine
- Dibenzepin
- Digoxin
- Disopyramide
- Dofetilide
- Dolasetron
- Domperidone
- Donepezil
- Droperidol
- Duloxetine
- Efavirenz

- Encorafenib • Enflurane • Entrectinib • Erythromycin
- Escitalopram
- Etrasimod
- Etravirine
- Fedratinib
- Fexinidazole
- Fingolimod
- Flecainide
- Fluoxetine
- Formoterol
- Foscarnet
- Fostemsavir
- Gatifloxacin
- Gemifloxacin
- Gepirone
- Glasdegib
- Gonadorelin
- Goserelin
- Granisetron
- Halofantrine
- Haloperidol
- Halothane
- Histrelin
- Hydroquinidine
- Hydroxychloroquine
- Hydroxyzine
- Ibutilide
- Iloperidone
- Imipramine
- Inotuzumab Ozogamicin

- IsofluraneIsradipineIvabradine
- Ivosidenib
- Lacosamide
- Lapatinib
- Lefamulin
- Lenvatinib
- Leuprolide
- Levofloxacin
- Lidocaine
- Lidoflazine
- Lofexidine
- Lopinavir
- Lorcainide
- Lumefantrine
- Macimorelin
- Mefloquine
- Methadone
- Metronidazole
- Mifepristone
- Mirabegron
- Mirtazapine
- Mobocertinib
- Moxifloxacin
- Nafarelin
- Nilotinib
- Norfloxacin
- Nortriptyline
- Octreotide
- Olanzapine
- Ombitasvir
- Ondansetron
- Osilodrostat

- OsimertinibOxaliplatinOzanimodPacritinibPaliperidone
- Panobinostat
- Paritaprevir
- Paroxetine
- Pasireotide
- Pazopanib
- Pentamidine
- Phenobarbital
- Pimavanserin
- Pirmenol
- Pitolisant
- Ponesimod
- Prajmaline
- Prilocaine
- Primidone
- Probucol
- Procainamide
- Prochlorperazine
- Promethazine
- Protriptyline
- Quetiapine
- Quinidine
- Quinine
- Quizartinib
- Ranolazine
- Relugolix
- Ribociclib
- Risperidone
- Selpercatinib

- Sematilide Sertindole Sertraline Sevoflurane Simeprevir • Siponimod Sodium Phosphate Sodium Phosphate, Dibasic Sodium Phosphate, Monobasic

  - Solifenacin
  - Sorafenib
  - Sotalol
  - Spiramycin
  - Sulfamethoxazole
  - Sulpiride
  - Sultopride
  - Sunitinib
  - Tacrolimus
  - Tedisamil
  - Telaprevir
  - Telithromycin
  - Tetrabenazine
  - Tizanidine
  - Toremifene
  - Trazodone
  - Triclabendazole
  - Trifluoperazine
  - Trimethoprim
  - Trimipramine
  - Triptorelin
  - Vandetanib
  - Vardenafil
  - Vemurafenib
  - Venlafaxine

- Vilanterol
- Vinflunine
- Voclosporin
- Voriconazole
- Zolmitriptan
- Zotepine
- Zuclopenthixol

Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Cyclosporine
- Metoprolol
- Rifampin
- Rifapentine
- Theophylline
- Tolterodine
- Warfarin

#### Interactions with Food/Tobacco/Alcohol

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following is usually not recommended, but may be unavoidable in some cases. If used together, your doctor may change the dose or how often you use this medicine, or give you special instructions about the use of food, alcohol, or tobacco.

- · Grapefruit Juice
- Tobacco

### **Other Medical Problems**

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- · Asthma or
- Bronchitis or
- Emphysema—Propafenone can increase trouble in breathing.
- · AV block (type of abnormal heart rhythm), with no pacemaker or

- · Bradycardia (slow heartbeat) or
- Breathing problems or lung disease (eg, bronchospasm, severe obstructive pulmonary disease) or
- · Brugada syndrome (a genetic heart rhythm disorder) or
- Cardiogenic shock (shock caused by heart attack) or
- · Heart failure or
- Hypotension (low blood pressure) or
- · Mineral imbalance or
- Sick sinus node syndrome (type of abnormal heart rhythm), with no pacemaker—Should not be used in patients with these conditions.
- Blood or bone marrow problems (eg, agranulocytosis, granulocytopenia) or
- · Coronary artery disease or
- Heart rhythm problems (eg, QT prolongation) or
- Myasthenia gravis (severe muscle weakness) or
- Torsade de pointes or
- Ventricular fibrillation or tachycardia—Use with caution. May make these conditions worse.
- · Kidney disease or
- Liver disease—Use with caution. The effects may be increased because of slower removal of the medicine from the body.
- If you have a permanent pacemaker—Use with caution. Propafenone may interfere with the pacemaker and require more careful follow-up by the doctor.

## Proper use of Rythmol SR

Take this medicine exactly as directed by your doctor. Do not take more or less of this medicine, and do not take it more often than your doctor ordered.

This medicine comes with a patient information leaflet. Read and follow the instructions carefully. Ask your doctor if you have any questions.

For patients taking the extended-release capsules:

- Swallow the capsules whole. Do not crush, break, or chew them.
- This medicine may be taken with or without food.

This medicine works best when there is a constant amount in the blood. To help keep the amount constant, do not miss any doses. Also, it is best to take each dose at evenly spaced times day and night. For example, if you are to take 3 doses a day, doses should be spaced about 8 hours apart. If you need help in planning the best times to take your medicine, check with your doctor.

Your doctor may want you to carry a medical identification card or bracelet stating that you are using this medicine.

## **Dosing**

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- The number of extended-release capsules or tablets that you take depends on the strength of the medicine.
- For atrial fibrillation (AF):
  - For oral dosage form (extended-release capsules):
    - Adults—At first, 225 milligrams (mg) every 12 hours. Your doctor may adjust your dose as needed. However, the dose is usually not more than 425 mg every 12 hours.
    - Children—Use and dose must be determined by your doctor.
  - For oral dosage form (tablets):
    - Adults—150 milligrams (mg) every 8 hours. Your doctor may increase your dose if needed.
    - Children—Use and dose must be determined by your doctor.

#### Missed Dose

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

## **Storage**

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Detailed Rythmol SR dosage information

## Precautions while using Rythmol SR

It is important that your doctor check your progress at regular visits to make sure the medicine is working properly. This will allow for changes to be made in the amount of medicine you are taking, if necessary.

This medicine can cause changes in your heart rhythm, such as conditions called PR, QRS, or QT prolongation. It may cause fainting or serious side effects in some patients. Contact your doctor right away if your symptoms do not improve or if they get worse.

Check with your doctor right away if you develop any of the following: chest pain, shortness of breath, swelling of your

hands, ankles, or feet, or weight gain. These may be symptoms of heart failure.

This medicine can temporarily lower the number of white blood cells in your blood, increasing the chance of getting an infection. If you can, avoid people with infections. Check with your doctor immediately if you think you are getting an infection or if you get a fever or chills, cough or hoarseness, lower back or side pain, or painful or difficult urination.

Make sure any doctor or dentist who treats you knows that you are using this medicine. This medicine may affect the results of certain medical tests.

Propafenone may cause some people to become dizzy or lightheaded. *Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are dizzy.* 

If you have been using this medicine regularly for several weeks, do not suddenly stop using it. Check with your doctor for the best way to gradually reduce the amount you are taking before stopping completely.

This medicine may decrease the amount of sperm men make. Talk to your doctor if you have concerns about this.

Grapefruits and grapefruit juice may increase the effects of propafenone by increasing the amount of this medicine in your body. You should not eat grapefruit or drink grapefruit juice while you taking this medicine.

Tell your doctor if you are smoking tobacco.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

## Side Effects of Rythmol SR

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

### Less common

- Chest pain
- · fast, irregular, or slow heartbeat
- · lightheadedness, dizziness, or fainting
- · shortness of breath
- swelling of the feet or lower legs
- · weight gain

#### Rare

- Chills
- fever
- joint pain
- · trembling or shaking

weakness

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

#### More common

· Change in taste or bitter or metallic taste

#### Less common

- Blurred vision
- constipation
- diarrhea
- · dryness of the mouth
- headache
- nausea or vomiting
- · skin rash
- · unusual tiredness or weakness

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Rythmol SR side effects (more detail)

## Related/similar drugs

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# Commonly used brand name(s)

#### In the U.S.

- Rythmol
- Rythmol SR

#### Available Dosage Forms:

- · Capsule, Extended Release
- Tablet

Therapeutic Class: Antiarrhythmic, Group IC

Chemical Class: Propafenone

## More about Rythmol SR (propafenone)

- · Check interactions
- Compare alternatives
- Reviews (17)
- Drug images
- · Side effects
- Dosage information
- During pregnancy
- Drug class: group I antiarrhythmics
- Breastfeeding

## **Patient resources**

### Other brands

Rythmol

## **Professional resources**

- Rythmol SR prescribing information
- Propafenone (AHFS Monograph)

#### Other brands

Rythmol

## Related treatment guides

- Ventricular Tachycardia
- Atrial Fibrillation
- Atrial Flutter
- Wolff-Parkinson-White Syndrome

## **Further information**

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

#### **DRUG STATUS**

#### **Availability**

Rx Prescription only

**Pregnancy & Lactation** 

ন্ত Risk data available

**CSA Schedule\*** 

N/A Not a controlled drug

**Approval History** 

Drug history at FDA

## **User Reviews & Ratings**

8.5 / 10

17 Reviews

## **Images**

Rythmol SR 425 mg (GS UY2 425)



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