

Package leaflet: Information for the user

ARYTHMOL 150 mg & 300 mg Tablets

Propafenone Hydrochloride

IMPORTANT INFORMATION

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 Arythmol is and what is it used for
2. What you need to know before you take Arythmol
3. How to take your Arythmol
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1. What Arythmol is and what is it used for

Arythmol contains the active substance propafenone hydrochloride.

Arythmol belongs to a group of medicines called anti arrhythmic agents.

Arythmol slows down the heart rate and helps to regulate the heartbeat. Arythmol tablets are used to treat and prevent arrhythmias (abnormal heart rhythms).

2. What you need to know before you take Arythmol

Do not take Arythmol:

- if you are allergic to propafenone hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you have a heart condition called Brugada Syndrome, which causes you to have a potentially life-threatening heart rhythm.
- if you had a heart attack in the previous 3 months.
- if you suffer from heart failure or any heart problems other than your abnormal heart rhythm.
- If you have a usually slow heart rate or hypotension (low blood pressure).

- If you suffer from any breathing problems, such as chronic bronchitis or emphysema.
- If your doctor has told you that you have a disturbance in the salts (e.g. sodium or potassium) in your blood.
- if you been diagnosed as having the condition known as myasthenia gravis?
- if you are taking ritonavir (antiviral agents)

Warnings and precautions

Talk to your doctor or pharmacist before taking Arythmol

- If you are pregnant or planning to become pregnant
- If you are breast feeding.
- If you suffer from any breathing problems, such as asthma

Take special care with Arythmol

- Tell your surgeon or dentist that you are taking Arythmol if surgery is planned. It may affect the anaesthetic used.
- If you have a pacemaker, it may need to be altered.
- Your doctor may perform ECGs and blood pressure monitoring prior to and during treatment to monitor your individual dose.

Children and adolescents

Arythmol is **NOT** suitable for children.

Other medicines and Arythmol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- medicines that affect the activity of the heart such as amiodarone, digoxin, quinidine
- tablets to prevent blood clots (e.g. warfarin)
- antibiotics (e.g. erythromycin or rifampicin)
- any of the group of medicines known as beta-blockers (these are used to treat high blood pressure)
- any antiviral agents (e.g. ritonavir)
- any of the group of medicines known as major tranquillisers, or an antidepressant of the tricyclic or related group (e.g. amitriptyline, dothiepin, desipramine)
- any other antidepressants, such as venlafaxine, fluoxetine, paroxetine
- cimetidine (an ulcer medicine)
- ciclosporin (an immunosuppressant, used after transplant operations, or in the treatment of arthritis or psoriasis)
- theophylline (used in the treatment of asthma)
- ketoconazole (an antifungal agent)
- phenobarbital (for epilepsy)

Arythmol with food and drink

Arythmol should not be taken with grapefruit juice.

Arythmol should be taken after food, with some water.

Pregnancy, breast-feeding and fertility

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

Driving and using machines

It is **NOT** advisable to drive, operate machinery or do anything that requires you to be alert until you know how the tablets affect you. This is because Arythmol can cause blurred vision, dizziness, tiredness and low blood pressure in some people.

Arythmol contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take your Arythmol

Always take this medicine as your doctor or pharmacist told you. Check with your doctor or pharmacist if you are not sure. The number of tablets that you will need to take will be decided by your doctor.

Adults

The recommended dose may be between one Arythmol 150 mg tablet three times a day to one Arythmol 300 mg tablet three times a day.

Elderly

You may need a lower dose of Arythmol if you are elderly, if you have problems with your kidneys or liver, or if you have a low bodyweight.

Use in children and adolescents

Arythmol is **NOT** suitable for children.



Swallow your tablets without chewing them. It is best to take them after food with some water. Do not take with grapefruit juice.

If you take more Arythmol than you should

If you or someone else takes more Arythmol than prescribed, you should contact a doctor or go to the nearest hospital casualty department **IMMEDIATELY**, taking your tablets and box with you, as this will allow easier identification of the tablets.

If you forget to take Arythmol

If you forgot to take a dose, take them as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all. Do not take a double dose to make up for a forgotten dose.

If you stop taking Arythmol

If you stop taking Arythmol without your doctor's advice, your condition may get worse. It is important that you keep taking these tablets until your doctor tells you to stop. Do **NOT** stop just because you feel better.

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 IMMEDIATELY if you develop any of the following conditions:

- seizures
- life threatening irregular heart beat
- heart problems which can cause shortness of breath or ankle swelling
- a rash, itching or skin reddening or other signs of an allergic reaction such as difficulty breathing. Although these are rare, they can be serious.
- yellowing of the skin and/or the whites of the eyes, as these may be a sign of liver problems (blockage of flow from the liver (cholestatis), inflammation of the liver (hepatitis)) or blood problems
- you start to bruise easily or if you develop a very sore throat with a high fever, as in very rare cases, treatment may affect the amount of white blood cells and platelets in the blood.

Other side effects with Arythmol may include:

Very Common side effects:

- Dizziness
- Heart palpitations (being aware of your heart beat)
- Heart rhythm disorders

Common side effects:

- Anxiety
- Difficulty sleeping
- Headache
- Alteration of taste or a bitter taste
- Blurred vision
- Abnormal heart rhythm
- Shortness of breath
- Stomach pain
- Feeling or being sick
- Diarrhoea

- Constipation
- Dry mouth
- Liver disorders
- Chest pain
- Feeling tired or weak
- Fever

Uncommon side effects:

- Loss of appetite
- Nightmares
- Fainting
- Ataxia (problems with or loss of coordination)
- Low blood pressure
- Vertigo (spinning sensation)
- A tingling or pricking sensation of the skin
- Numbness
- Bloating
- Flatulence (passing wind/gas)
- Redness of skin and itchy skin
- Impotence
- Irregular (slow or fast) heart beat

The following are side effects with an unknown frequency:

- Severe reduction in the number of white blood cells which makes infections more likely
- Confusion
- Tremor (feeling shaky)
- Rigidity (stiffness)
- Restlessness
- A fall in the blood pressure on standing up which may cause dizziness, lightheadedness or fainting
- Retching, stomach problems
- Lupus-like syndrome (an allergic condition which causes joint pain, skin rashes and fever)
- A reversible drop in sperm count has occasionally been reported with high doses
- Pustular skin eruptions.

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 Arythmol

Keep this medicine out of the sight and reach of children.

Do **NOT** use Arythmol after the expiry date printed on the packaging. The date refers to the last day of that month.

Do not store above 30°C.

If your doctor decides to stop the treatment, return any left over tablets to your pharmacist. Only keep the tablets if your doctor tells you to. Do not throw away any medicines via wastewater or household waste (e.g. down the toilet or in with your general rubbish). These measures will help protect the environment.

6. Contents of the pack and other information

What Arythmol contains

- The active substance is propafenone hydrochloride. Each tablet contains either 150mg or 300mg of propafenone hydrochloride.
- The other ingredients are microcrystalline cellulose, starch pregelatinised, hypromellose (Type 2910), sodium croscarmellose, purified water, macrogol 6000, titanium dioxide (E171), macrogol 400 and magnesium stearate.

What Arythmol looks like and contents of the pack

White to off white film coated, biconvex tablets. The inscription on the tablets is 150 or 300 on one side.

The tablets are available in two strengths containing either 150mg or 300mg of propafenone hydrochloride.

Each pack of Arythmol 150 mg tablets contains 90 tablets.

Each pack of Arythmol 300 mg tablets contains 60 tablets.

Marketing Authorisation Holder:

Mylan Products Ltd., 20 Station Close, Potters Bar, Herts, EN6 1TL, UK

Manufacturer:

Mylan Hungary Kft., Mylan utca 1, Komaron, H-2900, Hungary

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