

PACKAGE LEAFLET: Information for the patient

ARITMINE P

Film-coated tablets – 150 mg, 300 mg

(Propafenone hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- 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 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.

In this leaflet:

1. What Aritmine P is and what it is used for
2. Before you take Aritmine P
3. How to take Aritmine P
4. Possible side effects
5. How to store Aritmine P
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1. WHAT ARITMINE P IS AND WHAT IT IS USED FOR

Aritmine P contains the active substance propafenone hydrochloride, which belongs to a group of medicines called antiarrhythmics (class Ic). It acts by stabilizing the membrane of cardiac cells. Propafenone also demonstrates some β -blocking and calcium-channel blocking activity.

Aritmine P is indicated for the management of ventricular arrhythmias.

It is also indicated for the management of paroxysmal supraventricular tachyarrhythmias which include paroxysmal atrial flutter or fibrillation and paroxysmal re-entrant tachycardias involving the AV node or accessory pathway, where standard therapy is ineffective or contraindicated.

2. BEFORE YOU TAKE ARITMINE P

Do not take Aritmine P:

- if you are hypersensitive to propafenone or to any of the excipients mentioned in this leaflet (see section 6);
- if you have a heart rhythm disorder called 'Brugada syndrome';
- if you had a heart attack in the previous 3 months;
- in uncontrolled congestive heart failure;
- in cardiogenic shock (except arrhythmia induced);
- in severe bradycardia;
- in electrolyte disturbances;
- in severe obstructive pulmonary disease;
- in marked hypotension;
- in myasthenia gravis;
- if you are taking ritonavir.

Unless patients are adequately paced, Aritmine P should not be used in the presence of sinus node dysfunction, atrial conduction defects, second degree or greater AV block, bundle branch block or distal block.

Take special care with Aritmine P

Ask your doctor before you take Aritmine P.

It should be used with caution in:

- the elderly
- patients with heart failure;
- patients with pacemaker;
- hepatic or renal impairment;
- obstructive airways disease owing to beta-blocking activity.

There is potential for conversion of paroxysmal atrial fibrillation to atrial flutter with 2:1 or 1:1 conduction block.

Aritmine P tablets are not suitable for children.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

It is particularly important to inform your doctor that you are taking:

- *local anaesthetics* (e.g. intravenous lidocaine);
- *antiarrhythmics* (e.g. mexiletine, quinidine, amiodarone, dronedarone);
- *antiepileptics* (e.g. phenobarbital);
- *antibiotics* (e.g. clarithromycin, erythromycin, rifampicin);
- *antidepressants* (fluoxetine, desipramine, paroxetine, venlafaxine, fluvoxamine);
- *anticoagulants* (warfarin, fluindione, phenprocoumon);
- *beta-blockers* (antihypertensive drugs such as propranolol and metoprolol);
- *calcium channel blockers* (diltiazem, verapamil);
- *antifungal agents* (e.g. ketoconazole);
- *medicines used for prevention and treatment of nausea and vomiting* (e.g. rolapitant, tropisetron);
- *antivirals* (e.g. ritonavir, cobicistat);
- *antineoplastics* (e.g. idelalisib, crizotinib, imatinib);
- *cimetidine* (drug for ulcer treatment);
- *ciclosporin* (an immunosuppressant);
- *theophylline* (drug for the treatment of asthma);
- *digoxin* (cardiac glycoside);
- *eliglustat* (enzyme inhibitor).

Taking Aritmine P with food and drinks

Propafenone should not be taken with grapefruit juice because limited data suggest that it may inhibit the metabolism of propafenone.

Pregnancy

Inform your doctor or pharmacist if you are pregnant, think you might be pregnant or are planning to have a baby.

There are no adequate and controlled studies to date using propafenone in pregnant women. Propafenone should be used during pregnancy only when the potential benefits justify the possible risks to the fetus.

Breastfeeding

If you are breastfeeding, inform your doctor or pharmacist.

Propafenone is distributed in milk. Because of the potential for serious adverse reactions of propafenone in nursing infants, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug for the woman.

Driving and using machines

Propafenone hydrochloride tablets may cause blurred vision, dizziness, fatigue and hypotension which may affect the patient's speed of reaction. For this reason, it is recommended to avoid driving and using machines until it is known how propafenone tablets affect the patient.

3. HOW TO TAKE ARITMINE P

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

It is recommended that propafenone tablets should be initiated under direct hospital supervision with ECG monitoring and blood pressure control (if QRS interval prolongs by more than 20%, the dose should be reduced or the treatment should be discontinued until ECG returns to normal limits).

Patients weighing 70 kg and over: the initial recommended dose is 150 mg 3 times daily, after food. The dose may be increased at intervals of at least 3 days to 300 mg twice daily and, if necessary, to maximum 300 mg 3 times daily.

Patients weighing less than 70 kg: the dose should be reduced.

Elderly: may respond to lower doses.

Hepatic impairment: the dose should be reduced.

Children: Aritmine P tablets are not suitable for children.

If you take more Aritmine P than you should

If you take more Aritmine P than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

Limited information is available on the acute toxicity of propafenone.

Symptoms

Overdosage of propafenone may result in nausea and/or vomiting, hypotension, somnolence, bradycardia, intra-atrial and intraventricular conduction disturbances, and in rare cases seizures and high-grade ventricular arrhythmias.

Treatment

Effective management of propafenone overdosage requires early diagnosis and prompt detoxification, since no specific antidote is available.

If you forget to take Aritmine P

If you forget to take one dose, take the next dose in its usual time. Do not take a double dose to make up a forgotten dose.

If you stop taking Aritmine P

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 stop taking the tablets without your doctor's advice your condition may get worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Aritmine P can cause side effects, although not everybody gets them.

The frequency of possible side effects is evaluated as listed below:

Very common	may affect more than 1 in 10 people
Common	may affect 1 to 10 people from 100
Uncommon	may affect 1 to 10 people from 1,000
Rare	may affect 1 to 10 people from 10,000
Very rare	may affect less than 1 person from 10,000
Not known	Frequency cannot be estimated from the available data

Common or very common: constipation, diarrhoea, gastrointestinal disturbances, dry mouth, bitter taste, nausea, vomiting, chest pain, fatigue, fever, bradycardia, sino-atrial, atrioventricular, or intraventricular blocks, pro-arrhythmic effects, dizziness, restlessness, headache, sleep disorders, anxiety, blurred vision, heart palpitations, abnormal hepatic function, asthenia, dyspnoea.

Uncommon: anorexia, hypotension (including postural hypotension), extrapyramidal symptoms, paraesthesia, syncope, nightmares, erectile dysfunction (impotence), thrombocytopenia, blood disorders, hypersensitivity (including skin reactions), vertigo.

Frequency not known: jaundice, cholestasis, hepatitis, seizures, confusion, reduced sperm count, agranulocytosis, granulocytopenia, leucopenia, lupus-like syndrome, rigidity (stiffness).

Talk to your doctor or pharmacist if you get any of these side effects or any side effects not listed in this leaflet.

5. HOW TO STORE ARITMINE P

Keep out from the reach and sight of children!

Do not use Aritmine P after the expiry date which is stated on the package.

Store below 25°C!

Keep in the original package to protect it from light.

6. FURTHER INFORMATION

What Aritmine P contains

The active substance is propafenone hydrochloride.

Aritmine P 150 mg film-coated tablets:

Each film-coated tablet contains 150 mg propafenone hydrochloride.

Aritmine P 300 mg film-coated tablets:

Each film-coated tablet contains 300 mg propafenone hydrochloride.

The excipients are:

tablet core: starch, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, sodium starch glycolate, magnesium stearate

film coat: polyvinyl alcohol, titanium dioxide, macrogol, talc.

Contents of the pack

Aritmine P 150 mg: box with 30 film-coated tablets.

Aritmine P 300 mg: box with 30 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer

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