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

Aritmine P contains propafenone hydrochloride as active substance, 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 have:
- hypersensitivity to propafenone or to any of the other ingredients mentioned in this leaflet (see section 6);
- uncontrolled congestive heart failure;
- cardiogenic shock (except arrhythmia induced);
- severe bradycardia;
- electrolyte disturbances;
- severe obstructive pulmonary disease;
- marked hypotension;
- myasthenia gravis.

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 elderly and in patients with:
- heart failure;
- 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);
- *phenobarbital* (anticonvulsant);
- *antibiotics* (e.g. erythromycin, rifampicin);
- *antideppresants* (fluoxetine, desipramine, paroxetine, venlafaxine, fluvoxamine);
- *anticoagulants* (warfarin, fluindione, phenprocoumon);
- *beta-blockers* (antihypertensive drugs such as propranolol and metoprolol);
- *ketoconazole* (antifungal agent), *cimetidine* (drug for ulcer treatment), *ciclosporin* (an immunosuppressant), *theophylline* (drug for the treatment of asthma), *digoxin* (cardiac glycoside), *ritonavir* (antiviral).

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, or think you may 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 in nursing infants, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to 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 taking 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.
Gastrointestinal disorders: gastrointestinal disturbances, dry mouth, bitter taste.
Metabolism and nutritional disorders: anorexia.
Hepatobiliary disorders: jaundice, cholestasis, hepatitis.
General disorders and administration site conditions: chest pain, fatigue.
Cardiac disorders: bradycardia, sino-atrial, atrioventricular, or intraventricular blocks, pro-arrhythmic effects.
Vascular disorders: hypotension (including postural hypotension).
Nervous system disorders: dizziness, syncope, restlessness, headache, paraesthesia, seizures, sleep disorders, extrapyramidal symptoms.
Psychiatric disorders: anxiety, confusion.
Reproductive system and breast disorders: impotence, reduced sperm count.
Blood and lymphatic system disorders: blood disorders.
Musculoskeletal and connective tissue disorders: lupus syndrome.
Eye disorders: blurred vision.
Immune system disorders: hypersensitivity (including skin reactions).

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 away from 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 – Film-coated tablets, 150 mg:
Each film-coated tablet contains 150 mg propafenone hydrochloride.

Aritmine P – Film-coated tablets, 300 mg:
Each film-coated tablet contains 300 mg propafenone hydrochloride.

The other ingredients are: starch, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, sodium starch glycolate, magnesium stearate, opadry II white.

Contents of the pack
Aritmine P - 150 mg: box with 30 film-coated tablets.
Aritmine P - 300 mg: box with 30 film-coated tablets.

Explanatory of the illustration icons on the packaging:

According to medical prescription.

This medicine should not be taken by children.

Content. Warning. Tablet shape.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel. Fax: 00 355 4 23 62 800
Tirana - ALBANIA

This leaflet was formulated in January 2014..

SPECIFICATION

CROPING AREA 12 x 19 cm

PAY ATENTION, all the layers are visible.
If you have to print this document please check or uncheck the specific layers.