

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 more 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.

ARITMON 150 mg tablets

ARITMON 300 mg tablets

Propafenone

What is in this leaflet

1. What **ARITMON** is and what it is used for
2. What you need to know before you take **ARITMON**
3. How to take your **ARITMON**
4. Possible side effects
5. How to store **ARITMON**
6. Contents of the pack and other information

1. What **ARITMON** is and what it is used for

ARITMON contains the active substance propafenone hydrochloride. **ARITMON** belongs to a group of medicines called anti arrhythmic agents. **ARITMON** slows down the heart rate and helps to regulate the heartbeat. **ARITMON** tablets are used to treat and prevent arrhythmias (abnormal heart rhythms).

2. What you need to know before you take **ARITMON**

Do not take **ARITMON**:

- 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 **ARITMON**

- 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 **ARITMON**
- Tell your surgeon or dentist that you are taking **ARITMON** 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

ARITMON is NOT suitable for children.

Other medicines and **ARITMON**

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)

ARITMON with food and drink

ARITMON should not be taken with grapefruit juice.

ARITMON 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 **ARITMON** can cause blurred vision, dizziness, tiredness and low blood pressure in some people. **ARITMON** tablets contain lactose; if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

3. How to take your **ARITMON**

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 **ARITMON** 150 mg tablet three times a day to one **ARITMON** 300 mg tablet three times a day.

Elderly

You may need a lower dose of **ARITMON** 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

ARITMON 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 **ARITMON** than you should

If you or someone else takes more **ARITMON** 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 propafenone hydrochloride tablets 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 **ARITMON**

If you stop taking **ARITMON** 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 (cholestatics), 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 **ARITMON** 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.

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.

5. How to store ARITMON

Do not store above 25°C. Store in the original package. Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

6.Contents of the pack and other information

What ARITMON contains

- The active substance is propafenone hydrochloride. Each tablet contains either 150mg or 300mg of propafenone hydrochloride.
- The other ingredients are : lactose monohydrate, microcrystalline cellulose, povidone, sodium starch glycolate, sodium lauryl sulfate, magnesium stearate. Film: Opadry II white, purified water.

Contents of the pack:

Box of 30 (3x10) tablets of 150 mg propafenone in blister pack.
 Box of 60 (3x20) tablets of 150 mg propafenona in blister pack.
 Box of 30 (3x10) tablets of 300 mg propafenona in blister pack.

Manufacturer and Marketing Authorisation Holder:

ZADA Pharmaceuticals Ltd.
 Donji Bistarac without number
 75 300 Lukavac
 Bosnia and Herzegovina

Date and number of renewal of marketing authorization:

Aritmon, film-coated tablets, 30x150 mg :
Number: 04-07.3-2-4709/16 **Date:** 17.05.2017.
Aritmon, film-coated tablets, 60x150 mg :
Number: 04-07.3-2-4710/16 **Date:** 17.05.2017.
Aritmon, film-coated tablets, 30x300 mg :
Number: 04-07.3-2-4711/16 **Date:** 17.05.2017.

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