

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.



ZADARON tablets 200 mg
amiodarone

What is in this leaflet

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

1. What ZADARON is and what it is used for

ZADARON contains a medicine called amiodarone hydrochloride. This belongs to a group of medicines called anti-arrhythmics, class III. It works by controlling the uneven beating of your heart (called 'arrhythmias'). Taking the tablets helps your heartbeat to return to normal.

ZADARON tablets can be used to:

- Treat uneven heartbeats where other medicines either have not worked or cannot be used
- Treat an illness called Wolff-Parkinson-White Syndrome. This is where your heart beats unusually fast
- Treat other types of fast or uneven heartbeats known as 'atrial flutter' or 'atrial fibrillation'. **ZADARON** tablets are used only when other medicines cannot be used.
- Treat fast heartbeats which may happen suddenly and may be uneven. **ZADARON** tablets are used only when other medicines cannot be used.

2. What you need to know before you take ZADARON

Do not use ZADARON

- You are allergic (hypersensitive) to: iodine, amiodarone any of the other ingredients of **ZADARON** (listed in Section 6 below). Signs of an allergic reaction include: a rash, swallowing or breathing difficulties, swelling of your lips, face, throat or tongue
- You have a slower than usual heartbeat (called 'sinus bradycardia') or an illness called 'sino-atrial' heart block
- You have any other problems with your heartbeat and do not have a pacemaker fitted
- You have ever had thyroid problems. Your doctor should test your thyroid before giving you this medicine
- You are taking certain other medicines which could affect your heartbeat (see 'Taking other medicines' below)
- You are pregnant or breast-feeding (see 'Pregnancy and breast-feeding' below)

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking **ZADARON**.

Warnings and precautions

Talk to your doctor or pharmacist before taking **ZADARON** if:

- You have heart failure
- You have liver problems
- You have any problems with your lungs or have asthma
- You have any problems with your eyesight. This includes an illness called 'optic neuritis'
- You are about to have an operation
- You are elderly (over 65 years of age). The doctor will need to monitor you more carefully
- You have a pacemaker or implantable cardioverter defibrillator (ICD). Your doctor will check that your device is working properly shortly after you start taking the tablets or if your dose is changed
- You have blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson syndrome
- You have a severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body. You may also feel generally unwell, have a fever, chills and aching muscles (Toxic Epidermal Necrolysis).

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking **ZADARON**.

Protect your skin from sunlight

Keep out of direct sunlight while taking this medicine and for a few months after you have finished taking it. This is because your skin will become much more sensitive to the sun and may burn, tingle or severely blister if you do not take the following precautions:

- Make sure you use high factor sun cream
- Always wear a hat and clothes which cover your arms and legs.

Tests

Your doctor will take regular tests to check how your liver is working. **ZADARON** can affect how your liver works. If this happens, your doctor will decide whether you should keep taking these tablets. Your doctor may do regular thyroid tests while you are taking this medicine. This is because **ZADARON** tablets contain iodine which can cause problems to your thyroid.

Your doctor may also do other regular tests such as blood tests, chest X-rays, ECG (electrical test of your heartbeat) and eye tests both before and while you are taking **ZADARON**.

Children and adolescents

ZADARON should not be given to children and adolescents.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines. This includes medicines you buy without prescription, including herbal medicines.

In particular, do not take this medicine and tell your doctor, if you are taking:

- Other medicines for an uneven heartbeat (such as solatol, quinidine, procainamide, disopyramide or bretylium)
- Medicines for infections (such as intra-venous erythromycin, co-trimoxazole, moxifloxacin or pentamidine)
- Medicines for schizophrenia (such as chlorpromazine, thioridazine, fluphenazine, pimozide, haloperidol, amisulpride or sertindole)
- Medicines for other mental illnesses (such as lithium, doxepin, maprotiline or amitriptyline)
- Medicines for malaria (such as quinine, mefloquine, chloroquine or halofantrine)
- Medicines used for hay fever, rashes or other allergies called antihistamines (such as terfenadine, astemizole or mizolastine)
- Cisapride and vincamine

Tell your doctor if you are taking any of the following medicines:

- Medicines that lengthen your heart beat (the QT interval) such as medicines for infection (such as clarithromycin, ciprofloxacin, ofloxacin or levofloxacin)
- Medicines for heart problems called beta-blockers (such as propranolol)
- Medicines called calcium channel blockers – for chest pain (angina) or high blood pressure (such as diltiazem or verapamil)
- Medicines for constipation (laxatives) such as bisacodyl or senna
- Medicines for high cholesterol (statins) such as simvastatin or atorvastatin

The following medicines can increase the chance of you getting side effects, when taken with ZADARON:

- Amphotericin (when given directly into a vein) – used for fungal infections
- Medicines for inflammation (corticosteroids) such as hydrocortisone, betamethasone or prednisolone
- Water tablets (diuretics)
- General anaesthetics or high dose oxygen – used during surgery
- Tetracosactide – used to test some hormone problems

ZADARON may increase the effect of the following medicines:

- Ciclosporin and tacrolimus – used to help prevent rejection of transplants
- Medicines for impotence such as sildenafil, tadalafil or vardenafil
- Fentanyl – used for pain relief
- Ergotamine – used for migraines
- Midazolam – used to relieve anxiety or to help you relax before surgery
- Colchicine – used for the treatment of gout
- Flecainide – another medicine used for uneven heartbeats. Your doctor should monitor your treatment and may half your dose of Flecainide
- Lidocaine – used as an anaesthetic
- Warfarin – used to stop your blood from clotting
- Digitalis – used for some heart conditions
- Dabigatran – used to thin the blood.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking ZADARON.

Taking ZADARON with food and drink

Do not drink grapefruit juice while taking this medicine. This is because drinking grapefruit juice while taking **ZADARON** can increase your chance of getting side effects.

Pregnancy and breast-feeding and fertility

- Tell your doctor before taking this medicine if you are pregnant, might become pregnant or think you may be pregnant. **ZADARON** tablets are not normally given during pregnancy
- Do not take if you are breast-feeding or plan to breast-feed. This is because small amounts of this medicine may pass into the mothers' milk. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

You may have blurred eyesight after taking this medicine. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of ZADARON 200 mg tablets

This medicine contains:

- **Lactose (a type of sugar):** If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine

• **Iodine:** Iodine is present in Amiodarone hydrochloride, the medicine your tablets contain. Iodine can cause problems to your thyroid (see 'Tests' below)

3. How to take ZADARON

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

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole.

Adults

- The usual starting dose is 200mg (one 200mg ZADARON tablet) three times each day for one week
- The dose will then be lowered to 200mg twice each day for one week
- The dose will then be lowered to 200mg once each day, until you are told otherwise
- In some cases, your doctor may then decide to either increase or lower the amount you take each day. This will depend on how to react to this medicine

Children and adolescents

ZADARON should not be given to children and adolescents.

Elderly

The doctor may give you a lower dose of ZADARON. Also, the doctor should check your blood pressure and thyroid function regularly.

If you take more ZADARON than you should

If you take more ZADARON than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

If you forget to take ZADARON

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten tablet.

If you stop taking ZADARON

Keep taking ZADARON until your doctor tells you to stop. Do not stop taking ZADARON just because you feel better. If you stop taking this medicine the uneven heartbeats may come back. This could be dangerous.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Stop taking ZADARON 200 mg tablets and see a doctor or go to a hospital straight away if:

Common (affects less than 1 in 10 people)

- You get yellowing of the skin or eyes (jaundice), feel tired or sick, loss of appetite, stomach pain or high temperature. These can be signs of liver problems or damage, which can be very dangerous.
- Difficulty breathing or tightness in the chest, coughing which will not go away, wheezing, weight loss and fever. This could be due to inflammation of your lungs which can be very dangerous.

Uncommon (affects less than 1 in 100 people)

- Your heartbeat becomes even more uneven or erratic. This can lead to a heart attack, so you should go to hospital straight away.

Very rare (affects less than 1 in 10,000 people)

- You get loss of eyesight in one eye or your eyesight becomes dim and colourless. Your eyes may feel sore or tender and feel painful to move. This could be an illness called 'optic neuropathy' or 'neuritis'.
- Your heartbeat becomes very slow or stops beating. If this happens go to hospital straight away.

Not Known (frequency cannot be estimated from the available data).

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swollen eyelids, face, lips, throat or tongue.
- Severe skin reactions including progressive skin rash with blistering and skin lesions (symptoms of a conditions called Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS).

Stop taking ZADARON and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

Uncommon (affects less than 1 in 100 people)

- Feeling numb or weak, tingling or burning feelings in any part of your body.

Very rare (affects less than 1 in 10,000 people)

- Skin rash caused by narrow or blocked blood vessels (called 'vasculitis')
- Headache (which is usually worse in the morning or happens after coughing or straining), feeling sick (nausea), fits, fainting, eyesight problems or confusion can occur. These could be signs of problems with your brain.
- Moving unsteadily or staggering, slurred or slow speech
- Feeling faint, dizzy, unusually tired and short of breath. These could be signs of a very slow heartbeat (especially in people over 65 years old) or other problems with your heart's natural beat

Not Known (frequency cannot be estimated from the available data)

- Chest pain and shortness of breath and irregular heartbeat. These could be signs of a condition called "Torsade de pointes"
- Some cases of bleeding in the lungs have been reported in patients taking ZADARON 200 mg tablets. You should tell your doctor straight away if you cough up any blood.

Tell your doctor as soon as possible if you have any of the following side effects:

Very common (affects more than 1 in 10 people)

- Blurred eyesight or seeing a coloured halo in dazzling light

Common (affects less than 1 in 10 people)

- Feeling extremely restless or agitated, weight loss, increased sweating and being unable to stand the heat. These could be signs of an illness called 'hyper-thyroidism'

- Feeling extremely tired, weak or 'run-down', weight gain, being unable to stand the cold, constipation and aching muscles. These could be signs of an illness called 'hypo-thyroidism'.
- Trembling when you move your arms or legs
- Blue or grey marks on parts of your skin exposed to sunlight, especially the face

Uncommon (affects less than 1 in 100 people)

- Muscle cramps, stiffness or spasm

Very rare (affects less than 1 in 10,000 people)

- Swelling of the testicles, impotency
- difficulty breathing, especially if you have asthma
- Red, scaly patches of skin, loss of hair or loosening of nails (called 'exfoliative dermatitis')
- Feeling tired, this could be sign of anaemia because of reducing number of red blood cells (this can be seen in blood tests)
- You may bleed or bruise more easily than usual. This could be because of a blood disorder (called 'thrombocytopenia')
- Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called 'syndrome of inappropriate anti-diuretic hormone secretion' (SIADH)

Not known (frequency cannot be estimated from the available data)

- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

Very common (affects more than 1 in 10 people)

- Feeling sick (nausea) or being sick (vomiting), change in the way things taste
- Changes in the amount of liver enzymes at the beginning of treatment. This can be seen in blood tests)
- Burning more easily in the sun (see 'Protect your skin from sunlight' in Section 2)

Common (affects less than 1 in 10 people)

- Slightly slower heartbeat
- Problems sleeping, Nightmares

Very rare (affects less than 1 in 10,000 people)

- Headache
- Hair loss, balding
- Skin rash
- Skin redness during radio-therapy
- Chronic liver disease
- Changes in creatinin levels(this can be seen in blood tests)

Not known (frequency cannot be estimated from the available data)

- Granulomas, small red lumps on the skin or inside the body which are seen by X-ray
- Hives (itchy, lumpy rash)
- Movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs (Parkinsonism)
- Feeling confused or seeing or hearing things that are not there
- A distorted sense of smell (parosmia)
- Dry mouth, constipation
- Feeling less hungry
- Difficulty in getting or maintaining an erection or in ejaculating
- Reduction in the number of white blood cells(this can be seen in blood tests)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store ZADARON

Do not store above 25°C. Store in the original pack .

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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What ZADARON contains?

Each ZADARON 200mg tablet contains 200mg of the active substance, amiodarone hydrochloride.

The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, povidone, crospovidone, magnesium stearate.

What ZADARON looks like and contents of the pack

ZADARON 200 mg tablets are uniform, round, slightly biconvex, white tablets. They are supplied as PVC / PVDC Aluminium blister packs in a carton box in pack sizes of 60(3 x 20) tablets.

Marketing Authorisation Holder and Manufacturer:

ZADA Pharmaceuticals d.o.o.

Donji Bistarac without number

75300 Lukavac, Bosnia and Herzegovina.

This leaflet was last revised in: November, 2016.

Data of first authorisation / renewal of the authorisation in BIH :

ZADARON 200 mg tablets Date: 08.11.2016. **Number:** 04-07.3-25196/15