

- Slow heartbeat.

Uncommon (may affect up to 1 in 100 people)

- Inflammation of the lungs (including scarring and thickening of the lungs). Signs include breathlessness or non-productive cough.

Rare (may affect up to 1 in 1,000 people)

- Liver problems including life threatening liver failure. Signs include stomach (abdominal) area pain or discomfort, loss of appetite, nausea, vomiting, yellowing of the skin or the whites of the eyes (jaundice), unusual darkening of the urine, fatigue (especially in association with other symptoms listed above), itching.
- Allergic reactions, including swelling of the face, lips, mouth, tongue or throat.

Other side effects include:

Very Common

- Changes in the results of one blood test: your blood creatinine level.
- Changes in your ECG (electrocardiogram) called QTc Bazett prolonged.

Common

- Problems with your digestive system such as indigestion, diarrhoea, nausea, vomiting and stomach pain.
- Feeling tired.
- Skin problems such as rash or itching.
- Change in the results of blood tests used to check your liver function.

Uncommon

- Other skin problems such as redness of the skin or eczema (redness, itching, burning or blistering).
- Your skin being more sensitive to the sun.
- Change in how things taste.

Rare

- Losing your sense of taste.
- Inflammation of blood vessels (vasculitis including leukocytoclastic vasculitis).

STORAGE CONDITIONS AND INSTRUCTIONS

- Store below 30°C in a dry place, protect from light.
- To be dispensed on the prescription of a registered medical practitioner only.
- Keep out of the reach of children.

PRESENTATION

Dronedon 400mg tablet is available in blister pack of 10's, 20's and 30's.

ہدایات:

- خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو 30°C سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
Kaizen Pharmaceuticals (Pvt.) Ltd.
E-127-129, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

ART No: 781

Dronedon
(D r o n e d a r o n e)

400mg Film Coated Tablets

Composition:

Each film coated tablet contains:
Dronedarone Hydrochloride Eq. to
Dronedarone 400 mg.

WARNING: HEART FAILURE

Increased risk of death, stroke, and heart failure in patients with decompensated heart failure or permanent atrial fibrillation. Do not use with permanent atrial fibrillation, symptomatic heart failure with recent decompensation requiring hospitalization, or NYHA Class IV heart failure.

MECHANISM OF ACTION

Dronedarone has sodium channel blockade, beta adrenergic blockade, cardiac repolarization, and calcium channel blockade effects (Class I, II, III, IV effects).

INDICATIONS

Dronedon contains an active substance named dronedarone. It belongs to a group of medicines called anti-arrhythmics that help regulate your heart beat.

Dronedon is used if you have a problem with your heart rhythm (your heart beats out of time - atrial fibrillation) and spontaneously, or through a treatment called cardioversion has changed your heartbeat back to normal rhythm.

Dronedon prevents repetition of your problem of irregular heart rhythm.

Dronedon is used only in adults.

Your doctor will consider all available treatment options before prescribing Dronedon to you.

CONTRAINDICATIONS

Do not take Dronedon

- If you have a problem with the nerves in your heart (heart block). Your heart might beat very slowly or you may feel dizzy. If you have had a pacemaker fitted for this problem, you can use Dronedon.
 - If you have a very slow heart beat (less than 50 beats a minute).
 - If your ECG (electrocardiogram) shows a heart problem called "prolonged QT corrected interval" (this interval is more than 500 milliseconds).
 - If you have a type of atrial fibrillation called permanent atrial fibrillation (AF). In permanent AF, the AF has been present for a long time (at least during 6 months) and a decision has been made not to change back your heart rhythm to atrial normal rhythm with a treatment called cardioversion.
 - If you have instability (drops) in your blood pressure which can lead to inadequate arterial blood flow to your organs.
 - If you have or had a problem where your heart cannot pump the blood round your body as well as it should (condition called heart failure). You may have swollen feet or legs, trouble breathing when lying down or sleeping, or shortness of breath when moving around.
 - If the percentage of blood leaving your heart each time it contracts is too low (condition called left ventricular dysfunction).
 - If you took amiodarone (another antiarrhythmic medicine) previously and experienced lung or liver problems.
 - If you take medicines for infection (including fungal infection or AIDS), allergies, heart beat problems, depression, after a transplant (see section below on "Other medicines and Dronedon"). This will give you more details on exactly what medicines you cannot take with Dronedon).
 - If you have a severe liver problem.
 - If you have a severe kidney problem.
 - If you take dabigatran.
- If any of the above apply to you, do not take Dronedon.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dronedon if

- You have a problem that gives you a low level of potassium or magnesium in your blood. This problem should be corrected before starting treatment with Dronedon.
- You are more than 75 years old.
- You have a condition when the vessel that supplies blood to heart muscle becomes hardened

and narrowed (coronary artery disease).

While taking Dronedon, tell your doctor if

- Your atrial fibrillation becomes permanent while you are taking Dronedon. You should stop taking Dronedon.
 - You have swollen feet or legs, trouble breathing when lying down or sleeping, shortness of breath when moving around, or weight increase (which are signs and symptoms of heart failure).
 - Tell your doctor immediately if you develop any of these signs and symptoms of liver problems: stomach (abdominal) area pain or discomfort, loss of appetite, nausea, vomiting, yellowing of the skin or the whites of the eyes (jaundice), unusual darkening of the urine, fatigue (especially in association with other symptoms listed above), itching.
 - You have breathlessness or non-productive cough. Tell your doctor, he/she will check your lung.
- If this applies to you (or you are not sure), please talk to your doctor or pharmacist before taking Dronedon.

Heart, lung and blood tests

While you are taking Dronedon, your doctor may perform tests to check your medical condition and how the medicine is working for you.

- Your doctor may look at your heart's electrical activity using an ECG (electrocardiogram) machine.
- Your doctor will order blood tests to check your liver function before you start taking Dronedon and during treatment.
- If you are taking some medicines against blood clot formation such as warfarin, your doctor will order a blood test called INR to check how well your medicine is working.
- Your doctor may also do other blood tests. The results of one of the blood tests to check kidney function (blood creatinine levels) may be changed by Dronedon. Your doctor will take this into account when checking your blood levels and will use another reference of the "normal" value of blood creatinine.
- Your doctor may check your lungs.

In some cases, Dronedon treatment may need to be stopped.

Please tell any other person who checks your blood that you are taking Dronedon.

Children and adolescents

Dronedon is not recommended in children and adolescents below 18 years of age.

Drug Interactions

Dronedon and some other medicines can affect each other and cause serious side effects.

You must not take any of the following with Dronedon:

- Other medicines used to control an irregular or fast heart beat such as flecainide, propafenone, quinidine, disopyramide, dofetilide, sotalol, amiodarone,
- Some medicines for fungal infections such as ketoconazole, voriconazole, itraconazole or posaconazole,
- Some medicines for depression called tricyclic antidepressants,
- Some tranquillising medicines called phenothiazines,
- Bepridil for chest pain caused by heart disease,
- Telithromycin, erythromycin, or clarithromycin (antibiotics for infections),
- Terfenadine (a medicine for allergies),
- Nefazodone (a medicine for depression),
- Cisapride (a medicine for food and acid reflux from your stomach to your mouth),
- Ritonavir (a medicine for AIDS infection),
- Dabigatran (a medicine for prevention of blood clot formation).

You must tell your doctor or pharmacist if you are taking any of the following medicines:

- Other medicines for high blood pressure, for chest pain caused by heart disease, or other heart problems, such as verapamil, diltiazem, nifedipine, metoprolol, propranolol or digoxin,
- Some medicines for reducing the cholesterol in your blood (such as simvastatin, lovastatin, atorvastatin, or rosuvastatin),
- Some medicines against blood clot formation such as warfarin, rivaroxaban, edoxaban and apixaban,
- Some medicines for epilepsy called phenobarbital, carbamazepine or phenytoin,
- Sirolimus, tacrolimus, everolimus and cyclosporine (used after a transplant),
- St John's Wort - a herbal medicine for depression,
- Rifampicin - for tuberculosis.

Dronedon with food and drink

Do not drink grapefruit juice while taking Dronedon. It can increase the blood levels of dronedarone and may increase your chance of getting side effects.

Pregnancy and breast-feeding

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

- Dronedon is not recommended if you are pregnant or you think you may be pregnant.
- Do not take Dronedon if you are a woman able to have children and you are not using a reliable contraceptive method.
- Stop taking your tablets and talk to your doctor straight away if you get pregnant while taking Dronedon.
- It is not known if Dronedon passes into your breast milk. You and your doctor should decide if you will take Dronedon or breastfeed. You should not do both.

Driving and using machines

Dronedon does not usually affect your ability to drive or use machine. However, your ability to drive and use machines may be affected by side effects such as tiredness.

Dronedon contains lactose

Lactose is a type of sugar. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

HOW TO TAKE Dronedon

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

Treatment with Dronedon will be overseen by a doctor who is experienced in the treatment of heart disease.

If you need to change from amiodarone (another medicine for irregular heart beat) to Dronedon, your doctor can provide special recommendations, for example pausing amiodarone before switching. Tell your doctor about all the medicines you take.

DOSAGE AND ADMINISTRATION

The usual dose is one 400 mg tablet twice a day. Take:

- one tablet during your morning meal and
- one tablet during your evening meal.

If you think that your medicine is too strong or too weak, talk to your doctor or pharmacist.

Taking this medicine

Swallow the tablet whole with water during a meal. The tablet cannot be divided into equal doses.

Over Dosage

Monitor the patient's cardiac rhythm and blood pressure. Treatment should be supportive and based on symptoms. There is no specific antidote available.

If you forget to take Dronedon

Do not take a double dose to make up for a forgotten tablet. Take the next dose when you are normally due to take it.

If you stop taking Dronedon

Do not stop taking this medicine without first talking to your doctor or pharmacist.

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

POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported with this medicine:

Talk to your doctor straight away, if you notice any of the following serious side effects — you may need urgent medical assistance

Very common (may affect more than 1 in 10 people)

- Problem where your heart does not adequately pump the blood round your body as well as it should (congestive heart failure) In clinical studies, this side effect was observed at a similar rate in patients receiving Dronedon and in patients receiving placebo. Signs include swollen feet or legs, trouble breathing when lying down or sleeping, shortness of breath when moving around, or weight increase.

Common (may affect up to 1 in 10 people)

- Diarrhoea, vomiting when excessive as it can lead to kidney problems.