

Package leaflet: Information for the patient

Dronedarone Aristo 400 mg film-coated tablets dronedarone

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. See section 4.

What is in this leaflet

1. What Dronedarone Aristo is and what it is used for
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1. What Dronedarone Aristo is and what it is used for

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

Dronedarone Aristo is used if you have a problem with your heart rhythm (your heart beats out of time – known as ‘atrial fibrillation’) and spontaneously, or through a treatment called ‘cardioversion’ has changed your heartbeat back to a normal rhythm.

Dronedarone Aristo prevents repetition of your problem of irregular heart rhythm.

Dronedarone Aristo is used only in adults.

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

2. What you need to know before you take Dronedarone Aristo

Do not take Dronedarone Aristo

- if you are allergic to dronedarone or to any of the other ingredients of this medicine (listed in section 6),
- 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 Dronedarone Aristo,
- 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 (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 (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 Dronedarone Aristo”. This will give you more details on exactly what medicines you cannot take with Dronedarone Aristo),
- if you have a severe liver problem,
- if you have a severe kidney problem
- if you take dabigatran (see section below on “Other medicines and Dronedarone Aristo”).

If any of the above apply to you, do not take Dronedarone Aristo.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dronedarone Aristo 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 Dronedarone Aristo.
- 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 Dronedarone Aristo, tell your doctor if

- your atrial fibrillation becomes permanent while you are taking Dronedarone Aristo. You should stop taking Dronedarone Aristo,
- 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),
- you develop any of these signs and symptoms of liver problems: stomach (abdominal) 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 Dronedarone Aristo.

Heart, lung and blood tests

While you are taking Dronedarone Aristo, 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 Dronedarone Aristo and during treatment.
- If you are taking some medicines to prevent 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 Dronedarone Aristo. 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, Dronedarone Aristo treatment may need to be stopped.

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

Children and adolescents

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

Other medicines and Dronedarone Aristo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may recommend that you use a medicine to prevent blood clot formation depending on your condition.

Dronedarone Aristo and some other medicines can affect each other and cause serious side effects. Your doctor may change the dose of any other medicines you are taking.

You must not take any of the following with Dronedarone Aristo:

- 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 tranquilising 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 to prevent 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 to prevent 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.

Dronedarone Aristo with food and drink

Do not drink grapefruit juice while taking Dronedarone Aristo. 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.

- If you are a woman able to have children, the doctor will do a pregnancy test before you start treatment with Dronedarone Aristo.
- Dronedarone Aristo is not recommended if you are pregnant or you think you may be pregnant.
- Do not take Dronedarone Aristo if you are a woman of child-bearing age and you are not using a reliable contraceptive method.
- Use effective birth control (contraception) during treatment and for 7 days after the final dose of Dronedarone Aristo.
- Stop taking your tablets and talk to your doctor straight away if you get pregnant while taking Dronedarone Aristo.
- It is not known if dronedarone passes into breast milk. You and your doctor should decide if you will take Dronedarone Aristo or breastfeed. Do not breastfeed during treatment with Dronedarone Aristo and for 7 days after the final dose.

Driving and using machines

Dronedarone Aristo 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.

Dronedarone Aristo contains lactose

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

3. How to take Dronedarone Aristo

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

Treatment with Dronedarone Aristo 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 Dronedarone Aristo, your doctor can provide special recommendations, for example pausing amiodarone before switching. Tell your doctor about all the medicines you take.

How much to take

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 a drink of water during a meal. The tablet cannot be divided into equal doses.

If you take more Dronedarone Aristo than you should

Contact immediately your doctor or the nearest emergency department or hospital. Take the medicine pack with you.

If you forget to take Dronedarone Aristo

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 Dronedarone Aristo

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.

4. Possible side effects

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

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 dronedarone 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.
- Slow heart beat.

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) 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 (may affect more than 1 in 10 people)

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

Common (may affect up to 1 in 10 people)

- problems with your digestive system such as 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 (may affect up to 1 in 100 people)

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

- losing your sense of taste,
- inflammation of blood vessels (vasculitis including leukocytoclastic vasculitis).

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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dronedarone Aristo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the blister and carton after “EXP.” The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice any visible sign of deterioration (see section 6).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dronedarone Aristo contains

- The active substance is dronedarone. Each film-coated tablet contains 400 mg of dronedarone (as hydrochloride).
- The other ingredients in the tablet core are hypromellose, pregelatinised maize starch, crospovidone, lactose monohydrate, colloidal anhydrous silica, magnesium stearate.
- The other ingredients in the tablet coat are hypromellose (E464), macrogol (E1521), titanium dioxide (E171).

What Dronedarone Aristo looks like and content of the pack

Dronedarone Aristo is a white, oblong shaped tablet with dimensions of 17.6 x 8.1 mm.

Dronedarone Aristo film-coated tablets are supplied in packs of 20, 20x1, 40, 40x1, 50, 50x1, 60, 60x1, 100 and 100x1 tablets in opaque PVC-Aluminium or opaque PVC/PE/PVDC-Aluminium blisters or perforated unit dose blisters.

Not all pack size may be marketed.

Marketing Authorisation Holder and Manufacturer

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