

Dronedarone

Cardiology Shared Care Guideline

Specialist Details

Name: _____
Location: _____
Tel: _____

Patient Identifier

Date: _____

Introduction

Licensed indication:

Dronedarone is indicated for the maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation (AF).

Adult Dosage and Administration

The recommended dose is 400 mg twice daily with food.

Available as: dronedarone 400mg tablets.

Hospital Specialist Responsibilities

- Assess patient's suitability for treatment with dronedarone.
- Arrange shared care with the patient's GP.
- Undertake Hospital Specialist monitoring as indicated in Table 1.
- Provide patient/carer with relevant (preferably written) information on use, side-effects and need for monitoring of medication.
- Review results of safety monitoring and request additional tests as required.
- Monitor disease response to treatment and need to continue therapy. Treatment should be stopped if any contraindications develop.
- Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed.
- Provide any other advice or information for the GP relating to dronedarone treatment.

Monitoring table

Test	Hospital Specialist	GP
ECG	Repeat ECG every 6-12 months or earlier if palpitation recurrence	
LFTs	At baseline	1 week and then 1 month after initiation of treatment, then monthly for 6 months, then at month 9, month 12 and periodically thereafter.*
U&Es	At baseline	<p>Measure serum creatinine 7 days after initiation—if raised**, measure again after a further 7 days.</p> <ul style="list-style-type: none"> • If creatinine continues to rise contact the specialist who reviews the patient in secondary care for advice. • If no further increase is seen, this value should be used as the new reference baseline.

* If ALT levels are > 3 x upper limit of normal (ULN) the specialist who reviews the patient in secondary care should be contacted.

** If clinically significant (e.g.>25%) contact specialist for advice.

GP Responsibilities

- Prescribe dronedarone according to dose advised by specialist.
- Arrange and record on-going monitoring as agreed with specialist: as indicated in Table 1.
- The onset of new dyspnoea or non-productive cough may possibly be related to pulmonary fibrosis (although this is rare); contact the specialist who reviews the patient in secondary care for advice.
- If there are recurrent symptoms suggestive of AF, arrange ECG and if AF recurrence is confirmed refer back to the specialist for further assessment.
- Report adverse drug reactions to specialist and usual bodies (e.g. MHRA/CHM).
- Ensure no drug interactions with other medicines

Adverse Effects, Precautions and Contraindications

Contraindications include: liver or lung toxicity associated with previous amiodarone use; second- or third-degree AV block; complete bundle branch block; distal block; sinus node dysfunction; atrial conduction defects or sick sinus syndrome (unless pacemaker fitted); permanent atrial fibrillation; bradycardia; prolonged QT interval; left ventricular systolic dysfunction, haemodynamically unstable patients; severe renal impairment (CrCl <30 ml/min); or severe hepatic impairment. **Medicines** that are contraindicated along with dronedarone are listed below.

Caution is advised when used in:

- Patients with coronary artery disease.
- Elderly patients > 75 years with multiple co-morbidities and clinical signs of heart failure.

Very common side effects are changes in blood creatinine levels and changes in ECG.

Common side effects include bradycardia, diarrhoea, vomiting, nausea, asthenia, abdominal pains and fatigue.

Skin and subcutaneous tissue disorders e.g. rashes, erythemas and photosensitivity reactions have been reported.

Rarely hepatocellular liver injury, including life-threatening acute liver failure has been reported in patients

treated with dronedarone; patients should immediately report any symptoms of potential liver injury e.g.

sustained new-onset abdominal pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine or itching.

Possible cases of **interstitial lung disease** including pneumonitis and pulmonary fibrosis have been reported.

Pregnancy: dronedarone is not recommended during pregnancy and in women of childbearing potential not using contraception, or while breast-feeding.

Common Drug Interactions

Dronedarone is contraindicated in combination with:

- CYP34A inhibitors including ketoconazole, itraconazole, voriconazole, posaconazole, telithromycin, clarithromycin, nefazodone and ritonavir.
- Potential torsades de pointes inducers including phenothiazines, cisapride, bepridil, tricyclic antidepressants, terfenadine and erythromycin.
- Citalopram, escitalopram, saquinavir: there is increased risk of ventricular arrhythmia.
- Fidaxomicin.
- Class I or III antiarrhythmics such as flecainide, propafenone, quinidine, disopyramide, dofetilide, sotalol, amiodarone. Note that amiodarone has a long half-life.
- Dabigatran.
- Edoxaban at a dose of 60mg daily (30mg once a day is recommended).

Dronedarone is not recommended in combination with:

- Grapefruit Juice.
- Potent CYP3A4 inducers including rifampicin, phenobarbital, carbamazepine, phenytoin, St John's Wort.
- Rivaroxaban: elimination may be reduced by dronedarone, clinical data are limited, and concurrent use is not recommended.

Use dronedarone with caution in association with:

- Beta-blockers, calcium antagonists: clinical and ECG assessment should be undertaken.
- Digoxin; there is an increased risk of digoxin-toxicity. Reduce digoxin dose by 50%, serum levels of digoxin should be closely monitored.
- Statins; use lower starting dose and maintenance doses due to increased risk of statin-induced myopathy.
- Fingolimod, bosutinib, ibrutinib, sirolimus, tacrolimus: use combination with caution.
- Vitamin K antagonists such as warfarin: INR should be closely monitored after initiating dronedarone
- Apixaban: dronedarone may increase the exposure to apixaban.

Communication

For any queries relating to this patient's treatment with dronedarone, please contact the specialist named at the top of this document.

This information is not inclusive of all prescribing information and potential adverse effects.
Please refer to full prescribing data in the SPC at www.medicines.org.uk or the BNF