

<b>SHARED CARE Guideline – Amber Traffic Light Classification</b>	
<b>Name of medicine</b>	Dronedarone
<b>Indication</b> <small>(including whether for adults and/or children)</small>	Treatment of paroxysmal atrial fibrillation or maintenance of sinus rhythm after successful cardioversion in Adults
<b>Author:</b> Andrea Lavous, Lead Cardiac Arrhythmia Nurse	
<b>Organisation:</b> Frimley Health NHS Foundation Trust	
<b>Date noted at ICS Medicines Board</b>	22 March 2023 (post approval at Drugs and Therapeutics Committee and Medicines Optimisation Board)

The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface.

This **AMBER** shared care sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer’s Summary of Product Characteristics. Prescribing must be carried out with reference to those publications whenever appropriate.

The SCG must be used in conjunction with the agreed core roles and responsibilities stated in annex A.

An agreement notification form is included in annex B for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

**Roles and Responsibilities**

Listed below are specific medicine/indication related responsibilities that are additional to those core roles and responsibilities that apply to all SCGs listed in annex A.

**Consultant / Specialist: Dronedarone will only be initiated by Cardiology and Arrhythmia Specialist Nurses**

1. Assess the patient. Establish the diagnosis and assess the patient’s ability to adhere to treatment.
2. Assess for contraindications and cautions and interactions.
3. Initiate treatment, and complete initial monitoring requirements.
4. Contact the GP requesting shared care for the patient, including this shared care protocol
5. The Arrhythmia Team will be available for verbal (or written) advice to the GP if the patient’s condition changes or deteriorates. Following this advice GP’s may refer patients back to the Cardiology Consultant if this is required.

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6. The Arrhythmia team will ensure the patient & carer(s) are given information regarding the treatment and a contact for the Arrhythmia team if they have any concerns
7. Following surgical treatment of AF (i.e. ablation) advise primary care whether treatment should be continued, and confirm the ongoing dose.

### Primary Care Prescriber

1. Monitor patient's overall health and wellbeing.
2. Prescribe the drug once the patient has been stabilised and care transferred
3. Report any adverse events to the hospital specialist, where appropriate
4. Monitor blood results and action any abnormal results as necessary

### Patient Relatives & Carers

As listed in agreed core roles and responsibilities for the shared care of medicines - annex A

### Key information on the medicine

Please refer to the current edition of the British National Formulary (BNF), available at <https://bnf.nice.org.uk/> and Summary of Product Characteristics (SPC), available at [www.medicines.org.uk](http://www.medicines.org.uk) for detailed product and prescribing information and specific guidance.

### Background to disease and use of medicine for the given indication

Dronedaronone is used in the treatment of arrhythmias as a second line option when other drugs are ineffective or contraindicated. It has a place in the treatment of severe cardiac rhythm disorders where other treatments either cannot be used or have failed. It has potential toxic adverse effects, and its use requires monitoring both clinically and via laboratory testing.

Due to the significant safety concerns, NHS England (NHSE) and NHS Improvement's [guidance](#) advises that prescribers should not initiate dronedaronone in primary care for any new patients. In exceptional circumstances, if there is a clinical need for dronedaronone to be prescribed, this must be initiated by a specialist and only continued under a shared care arrangement in line with NICE clinical guidance ([Atrial Fibrillation: NG 196](#)).

Where there is an existing cohort taking dronedaronone, it is recommended that these patients be reviewed to ensure that prescribing remains safe and appropriate.

Under a shared care arrangement, treatment must be recommended by a Consultant Cardiologist or Arrhythmia team. Initiation, dose titration, monitoring and prescribing for the first three months must be by the Consultant Cardiologist or Arrhythmia team. After the dose is stabilised, the patient can be transferred to the GP.

### Indication

Licensed indication: maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation.

NICE recommends dronedaronone as an option in patients:

- whose atrial fibrillation is not controlled by first-line therapy (usually including beta-blockers), that is, as a second-line treatment option and after alternative options have been considered and
- who have at least one of the following cardiovascular risk factors:

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- hypertension requiring drugs of at least 2 different classes
- diabetes mellitus
- previous transient ischaemic attack, stroke or systemic embolism
- left atrial diameter of 50 mm or greater or
- age 70 years or older and
- who do not have left ventricular systolic dysfunction and who do not have a history of, or current, heart failure

## Monitoring

Monitoring requirements including frequency and appropriate dose adjustments	Responsible clinician
<ul style="list-style-type: none"> <li>Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and ongoing monitoring be transferred to the GP.</li> </ul>	<i>Consultant Cardiologist or Arrhythmia team</i>
<p><b>Initiation:</b></p> <p><b>Baseline investigations:</b></p> <ul style="list-style-type: none"> <li>• Liver function tests</li> <li>• Urea and electrolytes, including potassium, magnesium, and serum creatinine</li> <li>• ECG</li> </ul> <p><b>Initial monitoring:</b></p> <ul style="list-style-type: none"> <li>• Liver function tests: after 7 days of treatment, and after 1 month of treatment</li> <li>• Urea and electrolytes: after 7 days of treatment, and after a further 7 days if any elevation is observed. If serum creatinine continues to rise then consideration should be given to further investigation and discontinuing treatment.</li> <li>• Monitor concurrent anticoagulant as appropriate</li> </ul>	<i>Consultant Cardiologist or Arrhythmia team</i>
<p><b>Maintenance:</b></p> <p><b>Ongoing monitoring:</b></p> <ul style="list-style-type: none"> <li>• ECG, at least every six months</li> <li>• Chest X-ray and pulmonary function tests if respiratory symptoms or toxicity suspected</li> <li>• Liver function tests monthly for the first 6 months of treatment, and at month 9 and month 12</li> <li>• Every 6 months thereafter</li> <li>• Urea and electrolytes every 6 months</li> <li>• Symptoms of heart failure ongoing</li> </ul>	<i>GP</i>

## Abnormal results – Actions to be taken

The GP may contact the initiating prescribing specialist for advice at any time if there are concerns.

The most commonly reported adverse reactions during treatment with dronedarone is bradycardia and gastrointestinal discomfort. For other side effects refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk)

**Cautions, contraindications:** Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk)

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<b>Adverse effects and managements</b> <b>Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme</b> <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a>	<b>Action</b>
<b>Renal function:</b> Electrolyte deficiency: hypokalaemia/ hypomagnesaemia	<ul style="list-style-type: none"> <li>Continue dronedarone. Correct deficiency as per local guidelines.</li> </ul>
Creatinine elevated	<ul style="list-style-type: none"> <li><b>Stop dronedarone</b> for any elevations of serum creatinine after the initial 7 days of treatment. Discuss urgently with specialist</li> </ul>
Creatinine clearance <30 mL/minute/ 1.73m <sup>2</sup>	<ul style="list-style-type: none"> <li><b>Stop dronedarone</b> and refer urgently to the specialist.</li> </ul>
<b>Cardiovascular:</b> Bradycardia: <ul style="list-style-type: none"> <li>Heart rate ≤ 60bpm</li> </ul>	<ul style="list-style-type: none"> <li>Continue dronedarone. Repeat monitoring.</li> </ul>
Heart rate ≤ 50bpm or ≤ 60bpm with symptoms	<ul style="list-style-type: none"> <li>Discuss with specialist team; dose reduction may be required</li> </ul>
ECG changes: worsening of arrhythmia, new arrhythmia, heart block, or QTc interval > 500 milliseconds	<ul style="list-style-type: none"> <li><b>Stop dronedarone.</b> Urgent referral to specialist team.</li> </ul>
Recurrence of atrial fibrillation	<ul style="list-style-type: none"> <li>Refer to specialist team; discontinuation should be considered.</li> <li>Discontinue dronedarone if patient develops permanent AF.</li> </ul>
Signs or symptoms of congestive heart failure, e.g. weight gain, dependent oedema, or increased dyspnoea.	<ul style="list-style-type: none"> <li><b>Stop dronedarone</b> if congestive heart failure develops.</li> </ul>
<b>Hepatotoxicity:</b> Serum transaminases >5xULN or any symptoms of hepatic injury	<ul style="list-style-type: none"> <li><b>Stop dronedarone.</b> Urgent referral to initiating specialist and hepatologist.</li> </ul>
Serum transaminases elevated >3xULN but no symptoms of hepatic injury	<ul style="list-style-type: none"> <li>Continue dronedarone and repeat LFTs in 48-72 hours. If still elevated <b>stop dronedarone</b> and discuss with specialist urgently.</li> </ul>

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Symptoms of hepatic injury (e.g. hepatomegaly, weakness, ascites, jaundice)	<ul style="list-style-type: none"> <li>• Check LFTs urgently; proceed as above.</li> </ul>
<b>Pulmonary toxicity:</b> new/worsening cough, shortness of breath or deterioration in general health (e.g. fatigue, weight loss, fever)	<ul style="list-style-type: none"> <li>• Continue dronedarone. Urgent referral to initiating specialist and respiratory specialist.</li> </ul>
<b>Gastrointestinal disturbance:</b> diarrhoea, nausea, vomiting, abdominal pain, dyspepsia	<ul style="list-style-type: none"> <li>• Continue dronedarone. May require dose reduction; discuss with specialist if persistent.</li> </ul>
<b>Nervous system disorders:</b> fatigue, asthenia	<ul style="list-style-type: none"> <li>• Continue dronedarone. May require dose reduction; discuss with specialist.</li> </ul>
<b>Dermatological disorders:</b> rashes, pruritus	<ul style="list-style-type: none"> <li>• Continue dronedarone. Reinforce appropriate self-care, including sun avoidance and purchasing of a wide spectrum sunscreen (at least SPF30) if photosensitivity occurs.</li> <li>• May require dose reduction; discuss with specialist.</li> </ul>

**Adverse effects and action to be taken (if appropriate)** - Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk)

**Drug interactions** - Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk)

### **Advice to patients and carers**

The specialist will counsel the patient about the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines

**The patient should be advised to report any of the following signs or symptoms to their GP without delay:**

- **Signs or symptoms of pulmonary toxicity**, e.g. breathlessness, non-productive cough or deterioration in general health (e.g. fatigue, weight loss, fever)
- **Signs or symptoms of liver injury**, e.g. abdominal pain, anorexia, nausea, vomiting, fever, malaise, fatigue, itching, dark urine, or jaundice
- **Signs or symptoms of heart failure**, e.g. development or worsening of weight gain, dependent oedema, or dyspnoea

Avoid grapefruit and grapefruit juice while taking dronedarone.

If taking a statin and dronedarone, to report any signs of unexplained muscle pain, tenderness, weakness or dark coloured urine.

### **Pregnancy, paternal exposure and breast feeding**

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with both the GP and the specialist

### **Pregnancy**

There are limited data on the use of dronedarone in pregnant women. Studies in animals have shown reproductive toxicity. Use is not recommended during pregnancy and in women of childbearing potential not using contraception.

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## **Breastfeeding**

Dronedarone is excreted into the breast milk in small amounts. Use is cautioned while breast feeding; infants should be monitored for adverse events such as diarrhoea, vomiting, weakness, bradycardia

## **Support and Advice Contact Details for Primary Care Prescribers:**

Name	Speciality	Telephone No.	Email address
Dr Mark Norman	Cardiology Frimley Park	Via switchboard	
Dr Peter Clarkson	Cardiology Frimley Park	Via switchboard	
Dr Andrew Cox	Cardiology Wexham Park	Via switchboard	
Dr Paresh Mehta	Cardiology Wexham Park	Via switchboard	
Farkhanda Majidy	Cardiology Pharmacist	Via switchboard	Farkhanda.majidy@nhs.net
Preya Fakira	Cardiology Pharmacist (Wexham Park hospital)	Via switchboard	Preya.fakira@nhs.net
Andrea Lavous	Lead Arrhythmia Nurse Frimley Park	0300 613 2641	Andrea.lavous@nhs.net
Louise Foster	Lead Arrhythmia Nurse Wexham Park	0791 763 6865	Louise.foster2@nhs.net
Medicines Information	Pharmacy	0300 613 4744	fhft.medicines.information@nhs.net

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## References:

- eBNF accessed via [www.medicinescomplete.com](http://www.medicinescomplete.com) on 12/04/2021
- Dronedarone hydrochloride 400 mg film-coated tablets (Multaq®). Sanofi. Date of revision of the text: 02/06/2020. Accessed via <https://www.medicines.org.uk/emc/product/497/> on 09/04/2021.
- Dronedarone hydrochloride 400 mg film-coated tablets (Dronedarone Aristo). Aristo Pharma. Date of revision of the text: 14/10/2020. Accessed via <https://www.medicines.org.uk/emc/product/497/> on 09/04/2021
- NHS England and NHS Clinical Commissioners. Aug 2019. [Items which should not be routinely prescribed in primary care: Guidance for CCGs](#). Accessed 09/04/2020
- MHRA. Drug Safety Update volume 5 issue 3: A1. October 2011. Dronedarone (Multaq ▼): cardiovascular, hepatic and pulmonary adverse events – new restrictions and monitoring requirements. Accessed via <https://www.gov.uk/drug-safety-update/dronedarone-multaq-cardiovascular-hepatic-and-pulmonary-adverse-events-new-restrictions-and-monitoring-requirements-on-09/04/2021>.
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- NICE. NG196: Atrial fibrillation: management. Last updated April 2021. Accessed via <https://www.nice.org.uk/guidance/ng196> on 28/04/21.
- Specialist Pharmacy Service- Suggestions for Therapeutic Drug Monitoring in Adults in Primary Care. September 2020. Accessed via <https://www.sps.nhs.uk/articles/suggestions-for-therapeutic-drug-monitoring-in-adults-in-primary-care-2/> on 12/04/2021.
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- LiverTox. Dronedarone. Last updated 05/01/2018. Accessed via <https://www.ncbi.nlm.nih.gov/books/NBK548208/> 12/04/2021.
- CredibleMeds. QTDrugs List. Clarithromycin. Last updated 31<sup>st</sup> March 2021. Accessed via <https://crediblemeds.org/druglist> on 26/04/21

## To be read in conjunction with the following documents

- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from <https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/>
- NHSE&I guidance – Items which should not be routinely prescribed in primary care: Guidance for CCGs. Available from <https://www.england.nhs.uk/publication/items-which-should-not-be-routinely-prescribed-in-primary-care-guidance-for-ccgs/>

NHSE policy – Responsibility for prescribing between primary & secondary/tertiary care. Available from

<https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/>

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## Annex A: Agreed core roles and responsibilities for the shared care of medicines

### Patients

- To be informed by initiating specialist, that the drug is a shared care drug and what this means.

### Relatives and Carers

- To support the patient.

### Consultant/ Specialist

#### Good Prescribing Guidelines

- Be aware that if you recommend that a colleague, for example a junior doctor or Primary Care Prescriber, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required <sup>(Ref GMC)</sup>.
- Be aware that if you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required.
- Be aware that you are asking the Primary Care Prescriber to take full medico-legal responsibility for the prescription they sign <sup>(Ref GMC)</sup>. For this reason the shared care guidelines (SCGs) are agreed at the Frimley Health NHS Foundation Trust Area Prescribing Committee with input from specialists and Primary Care Prescribers, and, for individual patients, the patient's Primary Care Prescriber must agree to take over responsibility before transfer of care, before the patient is discharged from specialist care.
- Be aware of the formulary status and the traffic light classification of the medicine you are prescribing within the Frimley Health Formulary.
- Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with a member of the Pharmacy team who will facilitate an update via the Frimley Health NHS Foundation Trust Area Prescribing Committee.
- Counsel patient on possible benefits, risks and side effects of the drug.

#### Before initiating treatment

- Evaluate the suitability of the patient for treatment, including consideration of the patient's current medication and any significant interactions.

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- Discuss and provide the patient with information about the reason for choosing the medicine, the likelihood of both harm and benefits, consequences of treatment, and check that their treatment choice is consistent with their values and preferences
- Advise patient of unlicensed status of treatment (including off-label use) if appropriate and what this may mean for their treatment.
- Explain shared care status of drug and what this means to the patient.
- Undertake baseline monitoring and assessment.

### Initiating and continuing treatment in secondary care

- Prescribe initial treatment and provide any associated training and counselling required.
- Inform the Primary Care Prescriber when initiating treatment so that the Primary Care Prescriber is aware what is being prescribed and can add to Primary Care Prescriber clinical record
- Continue to prescribe and supply treatment with appropriate monitoring until the patient's condition is stable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects.
- At any stage of treatment, advising Primary Care Prescriber of concerns regarding monitoring or potential adverse effects of treatment

### Transfer of care to Primary Care prescriber

- Liaise with the primary care prescriber to agree to share the patient's care and provide relevant accurate, timely information and advice.
- Only advise the patient that shared care will take place, and prescribing will be transferred, once the primary care prescriber has agreed to share responsibility of the patient care.
- If the primary care prescriber feels unable to accept clinical responsibility for prescribing then the consultant must continue to prescribe the treatment to ensure consistency and continuity of care.
- Ensure that the patient (and carer/relatives) are aware of their roles and responsibilities under the SCG
- Provide sufficient information and training for the patient to participate in the SCG

### Primary Care Prescriber

- Be aware of the formulary and traffic light status of the medicine you have been asked to prescribe.
- Be aware that Amber medicines have been assessed by the Frimley Heath Area Prescribing Committee as requiring careful transition between care settings but SCGs will be available to support safe transfer of care.
- It would be usual for Primary Care Prescribers to take on prescribing under a formal SCG. If you are uncertain about your competence to take responsibility for the patient's continuing care, you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient and make appropriate arrangements for their continuing care.
- Be aware that if you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence (Ref GMC).
- Be aware that if you prescribe, you will be responsible for any prescription you sign (Ref GMC).

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- Keep yourself informed about all the medicines that are prescribed for the patient
- Be able to recognise serious and/ or frequently occurring adverse side effects, and what action should be taken if they occur.
- Make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
- Keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition.
- Respond to requests to share care of patients in a timely manner, in writing (including use of form in annex B)
- Liaise with the consultant to agree to share the patient's care in line with the SCG in a timely manner.
- Continue prescribing medicine at the dose recommended and undertake monitoring requirements
- Undertake all relevant monitoring as outlined in the monitoring requirements section below, and take appropriate action as set out in this shared care guideline
- Monitor for adverse effects throughout treatment and check for drug interactions on initiating new treatments
- Inform the Consultant or specialist of any issues that may arise
- Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the share care guideline (e.g. ensuring the patient record is correct in the event of a patient moving practice).

**All**

- Where it has been identified that a SCG requires update e.g. new information needed, liaise with the SCG author and/or your organisation's Frimley Health NHS Foundation Trust Area Prescribing Committee representative who will facilitate an update at the Committee.

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# Appendix 1

**SHARED CARE PRESCRIBING GUIDELINE**  
**: Shared care agreement notification form for medicines and indications**  
**approved as amber on the Frimley Health NHS Foundation Trust Formulary**

## Agreement for transfer of prescribing to GP

Patient details

Name.....

Address.....

.....

.....

DOB.....

Hospital No.....

NHS No.....

<b>Name of medicine</b>	Dronedarone
<b>Discharge Dose</b>	
<b>Indication</b>	Treatment of paroxysmal atrial fibrillation or maintenance of sinus rhythm after successful cardioversion

Hospital/ Patient information		Practice information	
<b>Specialist Making Request</b>		GP Name:	
<b>Consultant</b>		Practice:	
<b>Speciality</b>		I agree to undertake shared care:	
<b>Drug name</b>		I do not agree to undertake shared care:	
<b>Dose</b>		If NOT please give reasons:	
<b>Next Prescription Due</b>		Signed:	
<b>Next Renal Profile</b>		Date:	
<b>Next LFTs</b>			
<b>Next ECG</b>			
Please refer to the Frimley Health NHS Foundation Trust Formulary for relevant shared care documents.			

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