**Request to Share Care and Agreement Form**

**Dronedarone for adults in the maintenance of sinus rhythm after successful cardioversion in clinically stable patients with paroxysmal or persistent atrial fibrillation Shared Care Protocol: Guideline No 18; Version 1**

**This Request to Share Care provides Key Primary Care Information on responsibilities and monitoring. The aim is to support the GP to agree to share care arrangements. Refer to Full Shared Care Protocol (SCP) for further information (page 5 onwards). This SCP is in line with** [**NHSE dronedarone SCP**](https://www.england.nhs.uk/publication/shared-care-protocols/)

**GP to review and must respond to provider Trust request to share care within 2 weeks using form provided on page 4.**

**For Completion by Specialist (with page 4 Shared Care Agreement Form)**

Addressograph label

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| **Patient name** |  |  |
| **DOB** |  | **OR** |
| **NHS number** |  |  |

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| **Drug(s) Dose and Route at handover:** |  |
| **Indication:** |  |
| **Date of first prescription by specialist:** |  |
| **Patient weight (kg):** |  |
| **Estimated date for prescribing to be continued by the GP:** |  |
| **Next monitoring tests due and dates** |  |
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| **Specialist additional comments/advice:** |  |
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| **Key Primary Care Information (refer to Full Shared Care Protocol for further information)**  **GP RESPONSIBILITIES**   |  |  | | --- | --- | | **GP/ Primary care prescriber responsibilities** | | | **1.** | Review the shared care request from the specialist to take on prescribing of dronedarone tablets. Promptly communicate to the specialist if prescribing responsibility is not accepted (within 2 weeks), including the clinical reason. Responsibility cannot be declined on grounds of cost of medication. | | **2.** | Check sufficient information has been provided to take on the responsibility for continued prescribing. Request any missing information to be provided from the specialist before taking on the prescribing in primary care. (Refer to point 7 of the ‘Specialist Responsibilities’ on page 6). | | **3.** | If accepted, prescribe ongoing treatment as detailed in the specialist’s request and as per (Adult dosage and administration section on page 5) taking into any account potential drug interactions (page 10) | | **4.** | Link dronedarone to the indication on the GP prescribing system. | | **5.** | Discuss and agree on ongoing monitoring to be done in primary care and conduct the required ongoing monitoring as discussed with the specialist and outlined below. Contact the specialist if any abnormal results as appropriate (see monitoring and actions to be taken if abnormal result section below). | | **6.** | Monitor patients during routine medication reviews for efficacy, adverse effects, adherence, and drug interactions. Contact the specialist for advice where necessary. Manage adverse effects as detailed in the (side effects and actions to be taken section on page 8) and discuss with specialist team when required.  Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). | | **7.** | Stop dronedarone and/or make an urgent referral to the specialist if worsening of arrythmia, hepatotoxicity, pulmonary toxicity or renal toxicity are suspected. | | **8** | Reinforce patient advice/responsibilities including when to seek medical attention. | | **9.** | Provide advice on the need for contraception to male and female patients at each review. Refer the management back to the specialist if the patient becomes or plans to become pregnant. | | **10.** | Stop treatment as appropriate and advised by the specialist. |      |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **MONITORING AND ACTIONS TO BE TAKEN**  **Monitoring**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Monitoring table** | | **Hospital specialist** | **Hospital specialist** | **GP** | | **Test** | **Indication** | **Pre-treatment baseline** | **Initial and (or) ongoing monitoring** | **Ongoing** | | Liver function tests (LFTs) particularly transaminases) | Baseline and ongoing assessment to confirm safe prescribing. | √ | Initially monitor after 7 days of treatment, then monthly for 6 months until prescribing is transferred to primary care. | Monitor at month 9 and month 12 then every 6 months thereafter. | | Urea and electrolytes (U&Es) and serum creatinine | Baseline and ongoing assessment to confirm safe prescribing. | √ | Initially monitor 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. | Every 6 months | | Electrocardiogram (ECG) | Baseline and ongoing assessment to confirm safe prescribing. | √ | Ongoing at least every six months | Ensure ECG has been done by specialists | | Chest X-ray and pulmonary function tests | Baseline assessment to confirm safe prescribing. | If needed. | If respiratory symptoms or toxicity suspected. | Not routinely required | | Monitor concurrent medicines as appropriate, e.g. anticoagulants, digoxin. | Dose stabilisation for concurrent medications | If clinically indicated. | If needed. | Not routinely required |   **Action to be taken if abnormal result**  Normal reference range may vary slightly between labs. Results should be recorded in the patient’s shared care monitoring record booklet (where in use). Please note an unusual fall or rise or a consistent downward or upward trend in any value should prompt review of the patient and extra vigilance. Some patients may have abnormal baseline values, specialist will advise.   |  |  | | --- | --- | | **Result** | **Action to be taken by GP** | | **Renal Function** |  | | Electrolyte deficiency | Continue dronedarone. Correct deficiency as per local guidelines. | | Creatinine elevated from baseline | **Stop dronedarone** for any elevations of serum creatinine which occur after transfer to primary care. Discuss urgently with specialist | | Creatinine clearance <30 mL/minute/ 1.73m2 | **Stop dronedarone** and refer urgently to the specialist. | | **Liver Function** |  | | Serum transaminases >5xULN or any symptoms of hepatic injury | **Stop dronedarone.** Urgent referral to initiating specialist and hepatologist | | ALT elevated >3xULN but no symptoms of hepatic injury. | Continue dronedarone and repeat LFTs in 48-72 hours. If still elevated **stop dronedarone** and discuss with specialist urgently. | | | |

* The expectation is that this information along with the full protocol provides sufficient information to enable GPs to be confident to take on the clinical & legal responsibility for prescribing and monitoring.
* Prescribing and monitoring responsibility will only be transferred under this shared care protocol when:
* Specialist has initiated treatment and prescribed/monitored treatment for initial stabilisation period of 6 months.
* Specialist has provided pre-treatment counselling and discussed patient responsibilities, preferences and obtained consent to shared care arrangements.
* Specialist and patient have completed and signed the shared care agreement form (page 4).

**Shared Care Agreement Form**

**This form is used to agree shared care between the specialist, patient and GP.**

**Specialist and patient agreement**

**By signing below we accept:**

* [Hertfordshire and West Essex (HWE) ICB Principles for Shared Care](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c)
* The requirements and responsibilities defined in this drug specific shared care protocol

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| **Specialist name:** | **Patient name or addressograph label:** |
| **Designation:** |
| **Provider Trust:** |
| **Direct telephone number:** |
| **Email:**  **Email (for use by GP to respond to request to share care):** |
| **Date:** | **Specialist Signature:** |

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| **Date:** | **Patient signature or specialist confirmation of patient agreement to shared care arrangement:** |

**GP response to shared care**

**Please return to specialist within two weeks of receipt of request to share care.**

***This form is to be completed by the GP who is requested to share care.***

* I agree to accept shared care for this patient as set out in this shared care protocol and [Hertfordshire and West Essex (HWE) ICB Principles for Shared Care](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c)
* I do not accept shared care for this patient
* My reason(s) for not prescribing are given below:

Please note that GP agreement is voluntary, with the right to decline to share care if for any reason you do not feel confident in accepting clinical responsibility. Refusal should not be for financial reasons.

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| **GP name:** | **Practice address /stamp:** |
| **Direct telephone number:** |
| **Email:** |
| **Date:** | **GP Signature:** |

**Please return a copy of the completed form to the requesting specialist within two weeks of receipt of request to share care (preferably by email).**

1. Specialist to retain copy in patient’s hospital records.
2. Copy to be given to patient.
3. GP to retain copy in patient’s notes

**Full Shared Care Protocol**

**Dronedarone for adults in the maintenance of sinus rhythm after successful cardioversion in clinically stable patients with paroxysmal or persistent atrial fibrillation**

**Shared Care Protocol: Guideline No 18; Version 1**

**This full protocol provides prescribing and monitoring guidance. It should be read in conjunction with** [Hertfordshire and West Essex (HWE) ICB Principles for Shared Care](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c)**,** [**Summary of Product Characteristics (SPC)**](https://www.medicines.org.uk/emc/product/10924/smpc) **and the** [**BNF**](https://bnf.nice.org.uk/drugs/dronedarone/#drug-action)**.**

**BACKGROUND AND INDICATION(S) FOR USE**

Dronedarone is used in the treatment of severe cardiac rhythm disorders, as a second line option when other drugs are ineffective or contraindicated. It has potentially serious adverse effects and its use requires monitoring both clinically and via laboratory testing. As per the [MHRA drug safety update](https://www.gov.uk/drug-safety-update/dronedarone-multaq-cardiovascular-hepatic-and-pulmonary-adverse-events-new-restrictions-and-monitoring-requirements), dronedarone has been associated with evidence of cardiovascular, hepatic and pulmonary risk and therefore it was proposed that it should only be prescribed after other treatment options have been considered. Furthermore, **patients prescribed dronedarone should have their treatment reviewed at the next routine appointment to ensure that they remain eligible for dronedarone treatment and regular monitoring of cardiac, liver, and renal function during treatment is recommended**. **Due to the safety concerns, dronedarone should not be initiated for new patients unless indicated and patients should be routinely reviewed for safety and continuity criteria**. **In exceptional circumstances, if there is a clinical need for dronedarone to be prescribed, this must be initiated by a specialist and may be continued in primary care under a shared care arrangement in line with NICE clinical guidance** ([Atrial fibrillation: NG 196](https://www.nice.org.uk/guidance/ng196/resources/atrial-fibrillation-diagnosis-and-management-pdf-66142085507269)). Dronedarone should be used as recommended in [NICE TA 197](https://www.nice.org.uk/guidance/ta197/chapter/1-Guidance) - Dronedarone for the treatment of non-permanent atrial fibrillation. Where there is an existing cohort taking dronedarone, it is recommended that these patients be reviewed to ensure that prescribing remains safe and appropriate.

This document applies to adults aged 18 and over.

**Licensed indications:**

As per NICE TA197 dronedarone is recommended as an option for the maintenance of sinus rhythm after successful cardioversion in people with paroxysmal or persistent atrial fibrillation:

• Whose atrial fibrillation is not controlled by first-line therapy (usually including beta-blockers), used as a second-line treatment option and after alternative options have been considered **and**

Who have at least 1 of the following cardiovascular risk factors:

• 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

This Shared Care Protocol **does not** cover any unlicenced prescribing of dronedarone.

**DOSAGE, ROUTE OF ADMINISTRATION AND DURATION OF TREATMENT**

* Transfer of monitoring and prescribing to primary care via the shared care protocol should only be done after the patient’s dose has been optimised and with satisfactory investigation results for at least 6 months.
* The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
* All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
* Termination of treatment will be the responsibility of the specialist.

**Swallowing difficulties**

Please refer to the [‘specials’ alternative guidance](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=2274&checksum=95f8d9901ca8878e291552f001f67692) for a list of commonly prescribed medicines and alternative methods of administration for patients with swallowing difficulties, feeding tubes or for patients prescribed unlicensed ‘specials’ medication. Each entry takes into account alternative medicines, formulations, cost and licensing. This list is not exhaustive. As not all medicines are listed, please contact the initiating specialist if required for individual patient advice if a patient has a swallowing difficulty.

**Initiation and ongoing dose regimen and administration**

* **Dose - 400mg twice daily, with morning and evening meals**.
* The starting and initial maintenance dose must be prescribed by the initiating specialist.
* Treatment should be initiated and monitored only under specialist supervision.

Pharmaceutical aspects



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| **SPECIALIST RESPONSIBILITIES INCLUDING PRE-TREATMENT ASSESSMENT**   |  |  | | --- | --- | | **Specialist Responsibilities** | | | **1.** | Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol and dronedarone is initiated for its licenced indications (see page 1 and 2). | | **2.** | Assess for appropriateness of treatment, contraindications, and cautions as well as interactions (see page 9). | | **3.** | Conduct required baseline investigations and initial monitoring (see page 2). | | **4.** | Discuss treatment with patient/carer including the following:   * benefits/risks with shared decision making and consent to treatment * counselling points (see page 7) * dose * monitoring requirements * potential side effects and actions * provide any relevant information and advice. | | **5.** | Initiate and optimise treatment for at least 6 months. Prescribe the maintenance treatment until optimised for at least 6 months and assess for clinical effectiveness and tolerability prior to transfer to primary care (see page 5). | | **6.** | Undertake routine specialist reviews and follow up appointments, which includes dose titration and monitoring, assessment of the response to treatment and tolerability (see page 2). Communicate the results to primary care. **After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring remains appropriate** | | **7.** | Once treatment is optimised, send this shared care protocol to patient’s GP practice requesting shared care, detailing the following:   * Diagnosis * Ongoing maintenance dose * Relevant test results * Monitoring requirements and when next due * Stopping and referral criteria * Specialist team contact details for GPs to obtain advice and support | | **8.** | Ensure that patient/carer is informed and made aware of their responsibilities (see patient/carer responsibilities). | | **9.** | Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care. | | **10.** | Provide advice on the need for contraception to male and female patients on initiation and at each review. Resume prescribing responsibilities if a patient becomes or wishes to become pregnant. | | **11.** | Provide advice to primary care on the management of adverse effects if required. | |

**GP RESPONSIBILITIES**

Refer to (page 1) and GP Considerations for Shared Care (page 11).

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| **PATIENT/ CARER RESPONSIBILITIES IN COOPERATION WITH SPECIALIST AND GP**   |  |  | | --- | --- | | **Patient/Carer responsibilities** | | | **1.** | Report to their specialist or GP if they do not have a clear understanding of or have any concerns with their treatment with dronedarone | | **2.** | Take dronedarone tablets as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist. | | **3.** | Inform the GP and specialist if pregnant or planning a pregnancy. | | **4.** | Following acceptance of shared care of prescribing by the GP, obtain further prescriptions for dronedarone tablets from the GP and not the specialist unless informed otherwise. | | **5.** | Inform their GP of any over the counter products and inform the community pharmacist that they are prescribed dronedarone when buying over the counter medications. | | **6.** | Avoid grapefruit juice while taking dronedarone | | **7.** | Use appropriate self-care against the possibility of phototoxic reactions (although this is uncommon): e.g. sun avoidance, protective clothing, avoiding tanning (including tanning beds) and to purchase and use a broad-spectrum sunscreen (at least SPF30). These measures to be continued for the duration of therapy. | | **8.** | If taking a statin and dronedarone to report any signs of unexplained muscle pain, tenderness, weakness or dark coloured urine. | | **9.** | Moderate alcohol intake to no more than 14 units per week to reduce the risk of hepatotoxicity. | | **10.** | Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop:   * Breathlessness, non-productive cough or deterioration in general health (e.g. fatigue, unplanned weight loss or gain, fever, heat and cold intolerance). * Abdominal pain, loss of appetite, nausea, vomiting, * Development or worsening of weight gain, dependent oedema, or dyspnoea * Dizziness, fatigue, fainting, shortness of breath, chest pain or palpitations, confusion or trouble concentrating | | **11.** | Attend for monitoring and review appointments with GP (and specialist) as requested; if patients miss monitoring/appointments, GPs may be unwilling to continue to supply dronedarone | |

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| **DISPENSING PHARMACIST RESPONSIBILITIES**   * Confirming that the patient has received verbal and written patient counselling / information and provide additional counselling should this be required. * Check the patient is being monitored regularly to ensure that it is safe before issuing or dispensing prescriptions. |

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| **MONITORING AND ACTIONS TO BE TAKEN**   * Refer to page 2. |

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| **SIDE EFFECTS/ADVERSE REACTIONS AND ACTIONS TO BE TAKEN (REFER TO** [**BNF**](https://bnf.nice.org.uk/drugs/dronedarone/#drug-action) **AND** [**SPC**](https://www.medicines.org.uk/emc/product/10924/smpc) **for full details)**   * GP to liaise with specialist if any side effects are a cause for concern. * Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) * For information on incidence of ADRs see relevant summaries of product characteristics  |  |  | | --- | --- | | **SIDE EFFECTS** | **Action to be taken by GP** | | **Cardiovascular** |  | | Bradycardia:  Heart rate 50 - 60bpm without symptom | Continue dronedarone. Repeat monitoring. No action required if hear rate remains >50 without symptoms. | | Heart rate ≤ 50bpm or ≤ 60bpm with  symptoms | Discuss with specialist team; dose reduction may be required. | | Worsening of arrhythmia, new arrhythmia, or heart block | **Stop dronedarone**. Urgent referral to specialist team. | | Recurrence of atrial fibrillation | Refer to specialist team; discontinuation should be considered. Discontinue dronedarone if patient develops permanent AF with a duration of six months or more. | | Worsening of arrhythmia, new arrhythmia, or heart block | **Stop dronedarone**. Urgent referral to specialist team. | | Signs or symptoms of **congestive heart failure,**  e.g. weight gain, dependent oedema, or  increased dyspnoea. | **Stop dronedarone** if congestive heart failure is suspected and refer urgently to specialist team. | | Symptoms of **hepatic injury** (e.g.  hepatomegaly, weakness, ascites, jaundice) | Check LFTs urgently;   * If serum transaminases >5xULN or any symptoms of hepatic injury - **Stop dronedarone.** Urgent referral to initiating specialist and hepatologist. * If ALT elevated >3xULN but no symptoms of hepatic injury. **Continue dronedarone** and repeat LFTs in 48-72 hours. **If still elevated** **stop dronedarone** and discuss with specialist urgently. | | **Pulmonary toxicity:**  New/worsening cough, shortness of breath or deterioration in general health (e.g. fatigue, weight loss, fever) | **Continue dronedarone**. Urgent referral to initiating specialist and respiratory specialist | | **Gastrointestinal disturbance:**  Diarrhoea, nausea, vomiting, abdominal pain, dyspepsia. | **Continue dronedarone**. May require dose reduction; discuss with specialist if persistent. | | **General disorders:**  fatigue, asthenia | **Continue dronedarone.** May require dose reduction; discuss with specialist. | | **Dermatological disorders:**  Rashes, pruritus, photosensitivity | **Continue dronedarone.** Reinforce appropriate self-care, including sun avoidance and purchasing of a broad-spectrum sunscreen (at least SPF30) if photosensitivity occurs. May require dose reduction; discuss with specialist. | |

**CONTRAINDICATIONS AND PRECAUTIONS** **(REFER TO** [**BNF**](http://www.bnf.org/bnf/index.htm) **AND** [**SPC**](http://www.medicines.org.uk/emc) **for full details)**

* Known hypersensitivity to dronedarone or any of the excipients.
* Second- or third-degree atrio-ventricular block, complete bundle branch block, distal block, sinus node dysfunction, atrial conduction defects, or sick sinus syndrome (except when used in conjunction with a functioning pacemaker).
* Bradycardia less than 50 beats per minute.
* Permanent atrial fibrillation (AF) with an AF duration ≥6 months (or duration unknown), and attempts to restore sinus rhythm no longer considered by the physician.
* Unstable haemodynamic conditions.
* History of or current heart failure, or left ventricular systolic dysfunction.
* Patients with liver or lung toxicity related to previous use of dronedarone.
* Co-administration with potent cytochrome P450 3A4 (CYP3A4) inhibitors, such as ketoconazole, itraconazole, voriconazole, posaconazole, telithromycin, clarithromycin, nefazodone and ritonavir (see page 9).
* Co-administration with medicinal products inducing torsades de pointes, including phenothiazines, cisapride, bepridil, tricyclic antidepressants, terfenadine and certain oral macrolides (such as erythromycin), class I and III anti-arrhythmics (see page 9).
* Co-administration with dabigatran.
* QTc Bazett interval greater than 500 milliseconds
* Severe hepatic or renal impairment (CrCl <30 mL/min)
* Pregnancy - There is 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

**Cautions:**

* Dronedarone can cause serious adverse reactions; clinical monitoring for development of congestive heart failure, left ventricular systolic dysfunction, QTc prolongation, liver injury, and respiratory disease are required (see page 2).
* Low levels of dronedarone are anticipated in breast milk. Use is cautioned while breast feeding. Infants should be monitored for adverse events such as diarrhoea, vomiting, weakness, bradycardia.

**NOTABLE DRUG INTERACTIONS (REFER TO** [**BNF**](http://www.bnf.org/bnf/index.htm) **AND** [**SPC**](http://www.medicines.org.uk/emc) **for full details)**

Dronedarone is contraindicated when co-administered with potent cytochrome P450 3A4 (CYP3A4) inhibitors, medicinal products inducing torsades de pointes, and dabigatran (see above).

Dronedarone is an enzyme inhibitor and can increase exposure to a number of medicines including:

* P-glycoprotein (PgP) substrates (e.g. digoxin, dabigatran, apixaban, rivaroxaban, edoxaban).
* CYP3A4 substrates (e.g. ciclosporin, statins, fentanyl, sildenafil, tacrolimus, sirolimus, everolimus, apixaban, rivaroxaban, edoxaban).
* CYP2D6 substrates (e.g. metoprolol).

Dronedarone interacts with other medicines that:

* Induce Torsade de Points or prolong QTC (e.g. Phenothiazines, cisapride, bepridil, tricyclic antidepressants, certain oral macrolides (such as clarithromycin and erythromycin), terfenadine and Class I and III anti-arrhythmics due to risk of proarrythmis. Concomitant use is contraindicated.
* Lower heart rate (e.g. Beta-blockers, calcium channel blockers).
* Induce hypokalaemia (e.g. Diuretics, stimulant laxatives).
* Induce hypomagnesaemia (e.g. Diuretics).

Other interactions include:

* CYP3A4 inhibitors – may increase exposure to dronedarone (e.g. ketoconazole, itraconazole, voriconazole, posaconazole, ritonavir, clarithromycin, grapefruit juice). Concomitant use is contraindicated.
* P-gp substrates such as digoxin and anticoagulants (vitamin K antagonist and direct oral anticoagulant (DOAC)) - exposure may be increased by dronedarone.
* Potent CYP3A4 inducers – may reduce exposure to dronedarone and are not recommended (e.g. rifampicin, phenobarbital, carbamazepine, phenytoin, St John’s Wort).

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| **CONTACT DETAILS for BACK-UP INFORMATION / ADVICE**  **East and North Hertfordshire NHS Trust**   |  |  |  |  | | --- | --- | --- | --- | | **Department** | **Specialist Team designated nhs.net email** | **Pharmacy Team shared care admin contact** | **Out of hours contact / switchboard** | | **Cardiology** | [enh-tr.cardiologycdh@nhs.net](mailto:enh-tr.cardiologycdh@nhs.net) | [sharedcare.enh-tr@nhs.net](mailto:sharedcare.enh-tr@nhs.net)  01438 284 032 | 01438 314333 |   **West Hertfordshire Hospitals NHS Trust**   |  |  |  |  | | --- | --- | --- | --- | | **Department** | **Contact Number** | **Specialist Team designated nhs.net email** | **Out of hours contact / switchboard** | | **Cardiology** | 01923 436 403 | [westherts.cardio@nhs.net](mailto:westherts.cardio@nhs.net) | WGH:  01923 244 366  HHGH: 01442 213 141  SACH: 01727 866 122 |   **Princess Alexandra Hospital NHS Trust**   |  |  |  |  | | --- | --- | --- | --- | | **Department** | **Contact number** | **Specialist Team designated nhs.net email** | **Out of hours contact / switchboard** | | **Cardiology** | 01279 827203/ 01279 827337 | [tpa-tr.cardiologyadminclinicalcorrespondence@nhs.net](mailto:tpa-tr.cardiologyadminclinicalcorrespondence@nhs.net) | 01279 444 455 |   **Communication**  For any queries relating to a patient’s treatment with dronedarone, please contact the specialist as documented at the top of this document. Read in conjunction with [Hertfordshire and West Essex Area Prescribing Committee (HWE APC) shared care principles](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c). For advice if you have any concerns contact the specialist team. If unable to contact specialist team or out of hours, contact medical registrar on call. |

**REFERENCES**

* National Institute for Health and Care Excellence (NICE)) (2021), NICE guideline [NG196]. Atrial fibrillation: diagnosis and management. Available at: https://www.nice.org.uk/guidance/ng196/resources/atrial-fibrillation-diagnosis-and-management-pdf-66142085507269 (Accessed: 10/05/2024).
* National Institute for Health and Care Excellence (NICE)) (2012), Technology appraisal guidance [TA197]. Dronedarone for the treatment of non-permanent atrial fibrillation. Available at: https://www.nice.org.uk/guidance/ta197 (Accessed: 13/05/2024)
* NHS Shared Care Protocols (SCPs), Dronedarone for patients within adult services. Available at: https://www.england.nhs.uk/publication/shared-care-protocols/#heading-6 (Accessed 13/05/2024).
* BNF Joint Formulary Committee. BNF (online) London: BMJ Group, Pharmaceutical Press, and RCPCH Publications (Accessed 10/05/2024)
* Electronic Medicines Compendium (emc), SmPC Dronedarone. Available at: https://www.medicines.org.uk/emc/product/10924/smpc (Accessed: 13/05/2024).
* Medicines and Healthcare products Regulatory Agency (MHRA) (2011), Dronedarone (Multaq▼): cardiovascular, hepatic and pulmonary adverse events – new restrictions and monitoring requirements. Available at: https://www.gov.uk/drug-safety-update/dronedarone-multaq-cardiovascular-hepatic-and-pulmonary-adverse-events-new-restrictions-and-monitoring-requirements. Accessed (13/05/2024)

**GP Considerations for Shared Care**

This shared care agreement outlines suggested management for the prescribing of the specified drug(s) and indication(s) when the responsibility is shared between the specialist and general practitioner (GP). Sharing of care assumes communication between the specialist, GP and patient. It is important that patients are consulted about treatment and are in agreement with it. The intention to share care should be explained to the patient by the doctor initiating treatment and consent obtained.

Prescribing is to be initiated in secondary care by a provider. **The expectation is that these shared care guidelines should provide sufficient information to enable GPs to be confident to take on the clinical and legal responsibility for the prescribing and the monitoring of this / these drug(s) in stable patients.** The questions below will help you confirm this:

* Is the patient’s condition predictable or stable?
* Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care document?
* Have you been provided with relevant clinical details including monitoring data?
* Have this document and BNF/SPC provided sufficient information for you to feel confident in accepting clinical and legal responsibility for prescribing?

**If you can answer YES to all of these questions (after reading this shared care guideline), then it is appropriate for you to accept the prescribing responsibility. GPs need to formally accept shared care by completing and returning the form provided within this protocol to the specialist within two weeks of receipt of request to share care.**

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should respond back to the consultant outlining your reasons for NOT prescribing on the agreement form within two weeks of receiving the request to share care. If you do not have the confidence to prescribe, you still have the right to decline. In such an event, the total clinical responsibility for prescribing the medication and any monitoring required remains with the specialist. Please note that medication cost is not an acceptable reason for refusal to take on shared care.

The prescribing doctor legally assumes clinical responsibility for the drug and the consequences of its useas well as responsibility of monitoring (securing and reviewing blood test results).

Prescribing and monitoring responsibility will only be transferred when the consultant and the GP agree that the patient’s condition is stable or predictable.

**Approval Information**

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| Title of Guideline | Dronedarone for adults in the maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation Shared Care Protocol |
| Guideline Number | 18 |
| Version | 1 |
| Effective Date | September 2024 |
| Review Date | This shared care guidance will be reviewed upon request in the light of new evidence becoming available |
| Original Version Produced | N/A |
| ***Approvals:*** |  |
| HWE ICB APC | September 2024 |
| Author/s | HWE ICB Pharmacy and Medicines Optimisation Team |
| Department(s) responsible for updating the guideline | HWE ICB Pharmacy and Medicines Optimisation Team |