SECONDARY CARE SECTION TO BE COMPLETED BY INITIATING DOCTOR

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| --- | --- | --- | --- |
| Patient’s Name: |  | NHS Number: |  |
| Date of Birth: |  | Date Treatment Started: |  |
|  | *(Add Date)* |
| One copy of information leaflet given to patient One copy of agreement sent to general practitioner One copy filed in patients notes |  |
| Name of Initiating Doctor: |  |  |
| Consultant: |  |  |
| Speciality: |  |  |
| Fax Number:  |  |  |
|  |  |  |

PRIMARY CARE SECTION TO BE COMPLETED BY GENERAL PRACTITIONER

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| I agree\*/don’t agree\* to enter into a shared care arrangement for the treatment of the above patient with this medicine (\*delete as appropriate) |
| GP Name: |  |  |
| Signature:  |  | Date: |  |
| Once signed please detach this sheet and fax to the number shown above.File copy in patient’s record and add read code 66S2 or XaK6z depending on GP clinical system. |

BACK-UP ADVICE AND SUPPORT

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| --- | --- | --- | --- | --- |
| Contact details | Telephone No. | Bleep: | Fax: | Email address: |
| Specialist: Dr Sanjiv Petkar(Consultant Cardiologist/Electrophysiologist) | 01902 694203 (sec), 01902 307999 Ext: 6667 |  | 01902 695646 | sanjiv.petkar@nhs.net |
| Specialist: Andrew Lapper(Arrhythmia Nurse Specialist) | 01902 694271 | 7811 |  | andrew.lapper@nhs.net |
| **Hospital Pharmacy Dept:**  | 01902 695133 |  |  |  |
| **Other:** Cardiac Pharmacist(Nazish Khan) | 01902 307999 | 7822 |  | nazish.khan@nhs.net |

**Patient’s Name: Date treatment commenced:**

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of dronedarone can be shared between the specialist and general practitioner (GP). GPs are **invited** to participate. If GPs are not confident to undertake these roles, then they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.**

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

Prescribing will be undertaken only by Consultant Cardiologists and Arrhythmia Nurse Specialist or only following consultation with these two groups to ensure appropriateness of use.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

**RESPONSIBILITIES and ROLES**

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| **Specialist responsibilities** |
| 1. Clarify place of drug in patients current therapy
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| 1. Review the patient's condition and monitor response to treatment regularly as outlined in the monitoring requirements below.
2. Undertake cardiac, hepatic and renal monitoring. To report any change in the clinical condition of the patient to the GP and provide advice regarding continuation/discontinuation of Dronedarone.
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| 1. Outline to the GP when therapy may be stopped assuming no improvement is recognised in the patient’s condition.
 |
| 1. Advise GPs of when to refer back, and when and how to stop treatment.
 |
| 1. Report adverse events to the CSM.
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| 1. Ensure clear backup arrangements exist for GPs, for advice and support.
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| 1. Give patients the information leaflet and card for Dronedarone and discuss the interaction with grapefruit juice.
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| **General Practitioner responsibilities** |
| 1. Reply to request to participate in shared care arrangement as soon as practicable.
2. To prescribe Dronedarone as requested by the Cardiology Consultant/Electrophysiology team
3. Liaise with the hospital Consultant regarding any complications of treatment.
4. Report suspected side effects to the Consultant and MHRA.
5. Report to and seek advice from the Specialist on any aspect of patient care that is of concern to the GP and that may affect treatment.
6. Refer back to the Specialist if the patient’s condition deteriorates.
7. Stop treatment if advised to do so by the Specialist.
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| **Patient's role** |
| 1. Read the information provided and give consent for the chosen treatment.
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| 1. Inform Consultant and GP of any other medication they may be taking or start taking during treatment, including over the counter medicines or herbal remedies.
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| 1. Store and handle medication safely.
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| 1. Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
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| 1. Share any concerns in relation to treatment with the Consultant/GP
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| 1. Report *any* adverse effects to the specialist or GP whilst taking Dronedarone
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| **SUPPORTING CLINICAL INFORMATION** |
| **Indications** |
| Dronedarone is indicated for the treatment of adult clinically stable patients with 1. paroxysmal atrial fibrillation or
2. persistent atrial fibrillation (AF) for the maintenance of sinus rhythm after successful cardioversion.

Dronedarone should not be given to patients with left ventricular systolic dysfunction or to patients with current or previous episodes of heart failure. **In this shared care agreement, Dronedarone is intended to be used in line with current recommendations and licensed indications:****(a) Licensed indication**: as above **(b) European Society of Cardiology Focused Update – For the Management of Atrial Fibrillation 2012**The 2012 ESC Atrial Fibrillation Guidelines have given Dronedarone as Class IA recommendation for the restoration and maintenance of sinus rhythm following successful cardioversion. The ESC states that:* Dronedarone is appropriate for maintaining sinus rhythm in patients with paroxysmal or persistent AF.
* Dronedarone should not be given to patients with moderate or severe heart failure, and should be avoided in patients with less-severe heart failure, if appropriate alternatives exist.

**(c) NICE Technology Appraisal 197 – October 2010**The licensing indications have been revised since the original recommendation by NICE following the publication of more scientific data. This drug is not suitable for patients with left ventricular systolic dysfunction or with current or previous episodes of heart failure. For the record the original recommendation of NICE was as follows: The National Institute of Clinical Excellence Technology Appraisal Guidance 197 recommends Dronedarone as an option for treatment of non permanent atrial fibrillation only in people:- whose atrial fibrillation is not controlled by first-line therapy (usually including beta-blockers), that is, as a second-line treatment option, **and** who have at least one of the following cardiovascular risk factors: − hypertension requiring drugs of at least two different classes − diabetes mellitus − previous transient ischaemic attack, stroke or systemic embolism − left atrial diameter of 50 mm or greater- left ventricular ejection fraction <40%− age 70 years or older, **and** who do not have unstable New York Heart Association (NYHA) class III or IV heart failure.  |
| Dosage and Administration |
| The dose of Dronedarone is 400mg twice daily and should be taken with meals Treatment with Dronedarone can be initiated in an outpatient settingIf a dose is missed, patients should take the next dose at the regular scheduled time and should not double the doseThere is no need for a loading dose or for titration. There is no clinically relevant interaction with warfarin**,** however, since Dronedarone is aP-glycoprotein inhibitor, it increases plasma concentrations of Dabigatran; therefore concomitant use of the two drugs has to be avoided.**Treatment with Class I or III antiarrhythmics (such as flecainide, propafenone, quinidine, disopyramide, dofetilide, sotalol, amiodarone) must be stopped before starting dronedarone.** A washout period of one month is recommended before dronedarone is started for patients currently receiving amiodarone. For patients receiving Dronedarone who are to receive amiodarone a washout period of two weeks is recommended. |
| Contraindications |
| * Hypersensitivity to the active substance or to any of the excipients.
* Second- or third- degree atrioventricular block or sick sinus syndrome (except when used in conjunction with a functioning pacemaker).
* Bradycardia <50 beats per minute (bpm).
* Permanent AF with an AF duration of ≥ 6 months (or duration unknown) and attempts to restore sinus rhythm no longer considered by the physician
* Patients in unstable hemodynamic conditions
* History of, or current heart failure or left ventricular dysfunction
* Patients with liver and lung toxicity related to previous use of amiodarone
* Co-administration with potent cytochrome P 450 (CYP) 3A4 inhibitors, such as ketoconazole, itraconazole, voriconazole, posaconazole, telithromycin, clarithromycin, nefadazone and ritonavir.
* Medicinal products inducing torsades de pointes such as phenothiazines, cisapride, bepridil, tricyclic antidepressants, terfenadine and certain oral macrolides, Class 1 and III antiarrhythmics.
* QTc Bazzett interval ≥ 500 milliseconds.
* Severe hepatic impairment.
* Severe renal impairment (CrCl <30ml/min)
 |
| Side Effects |
| **DronedaroneBLACK DOWN-POINTING TRIANGLE (9660)** is a black triangle drug. Continue to report to the MHRA and the Commission on Human medicines all suspected adverse reactions via the Yellow Card Scheme.Common side effects include diarrhoea, abdominal discomfort, rash, bradycardia, fatigue, asthenia, nausea, vomiting, raised creatinine ( GREATER-THAN OR EQUAL TO (8805)10% five days after treatment initiation, tubular secretion of creatinine is decreased without affecting GFR) and prolonged QT Interval.**Pregnancy/Lactation**Dronedarone is not recommended during pregnancy. It is not known whether Dronedarone is excreted in human breast milk. |
| **Monitoring** |
| *Cardiovascular Monitoring** + *Baseline ECG and at 6 monthly intervals to identify those who revert back to AF. Discontinuation of Dronedarone should be considered for these patients.*

*Hepatic Monitoring**LFTs should be taken before starting treatment with Dronedarone, after 1 week of treatment; monthly thereafter for the first 6 months of treatment, at month 9, at month 12 and periodically thereafter..* *Renal Monitoring** + *Creatinine levels should be measured before and 7 days after the initiation of Dronedarone. An increase in plasma creatinine (mean increase 10 micromol/L) has been observed with dronedarone 400 mg twice daily in healthy subjects and in patients. If an increase in creatininemia is observed, serum creatinine should be re-meaured after a further 7 days. If no further increase in creatinaemia is observed, this value should be used as the new reference baseline. If serum creatinine continues to rise, then consideration should be give to further investigation and discontinuing treatment.*

*An increase in creatininemia should not necessarily lead to the discontinuation of treatment with ACE inhibitors or angiotensin II receptor antagonists.* *Pulmonary Monitoring** + *Cases of interstitial lung disease, including pneumonitis and pulmonary fibrosis have been reported.*
	+ *Onset of dyspnoea or non-productive cough may be related to pulmonary toxicity.*
	+ *If suspected, relevant lung examinations should be undertaken and treatment discontinued if confirmed.*

***All cardiac, hepatic and renal monitoring will take place in secondary care under the supervision of the Cardiology/Electrophysiology team; prescribing can continue in primary care. Should there be any change in the clinical condition of the patient, this will be communicated to the patients GP and advice will be given regarding the continuation of Dronedarone.******Toxicity***

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| ***Parameter*** | ***Frequency of Monitoring*** | ***Result*** | ***Action*** |
| *ECG* | *Monitor ECG for QTc (Bazett) interval prolongation*  | *not greater than or equal to 500 milliseconds*  | *Refer to consultant* |
| *U&E* | *Will be monitored in secondary care; Creatine will be assessed at day 7 and any change will be taken as the patients new baseline. This will be communicated to the GP* |  | *use as a new baseline* |
| *LFTs* | *Prior to treatment**At week one**On a monthly basis for six months**At 9 months* *At 12 months and periodically thereafter* | *ALT levels >3xULN**if still >3xULN* *ULN = upper limit of normal* | *Retest**withdraw Dronedarone* |
| *Dyspnoea, cough, swelling of legs* | *Observe patients regularly for signs or symptoms of new or worsening heart failure* | *Worsening HF*  | *Refer to consultant* |

***Efficacy***

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| --- | --- | --- | --- |
| ***Parameter*** | ***Frequency of Monitoring*** | ***Result*** | ***Action*** |
| *ECG* | *For normalised sinus rhythm* |  |  |
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| **Drug Interactions** |
| *- Potent CYP3A4 inducers: such as rifampicin, phenobarbital, carbamazepine, phenytoin or St John’s Wort are not recommended and ketoconazole, itraconazole, voriconazole, posaconazole, telithromycin, clarithromycin, nefadazone and ritonavir are contraindicated**- Digoxin: Administration of dronedarone to patients receiving digoxin will bring about an increase in the plasma digoxin concentration and thus precipitate symptoms and signs associated with digoxin toxicity. A synergistic effect on heart rate and atrioventricular conduction is also possible. Halve the dose of digoxin. Clinical, ECG and digoxin blood level monitoring is recommended.* *- Beta blockers and calcium antagonists: The co-administration of beta-blockers or calcium antagonists with depressant effect on sinus and atrio-ventricular node should be undertaken with caution. These medicinal products should be initiated at low dose and up-titration should be done only after ECG assessment. In patients already on calcium antagonists or beta blockers at time of dronedarone initiation, an ECG should be performed and the dose should be adjusted if needed**- Statins: Statins should be used with caution. Lower starting dose and maintenance doses of statins should be considered and patients monitored for clinical signs of muscular toxicity**- Grapefruit juice: Patients should be warned to avoid grapefruit juice beverages while taking dronedarone**- Dabigatran: The co-administration of dronedarone with dabigatran is not recommended*  |
| **Vaccination** |
| The use of LIVE vaccine is not recommended during drug treatment with immunosuppressant drugs. *This section may be excluded if the shared care agreement related to a drug which is not an immunosuppressant.* |

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| **Version Control** |
| **Version** | **Date of Issue** | **Author/s** | **Brief Description of Changes** |
| 1.0 |  |  |  |