Shared Care Protocol

Dronedarone for non-permanent atrial fibrillation

NHS Somerset

Addressograph Label	
Surname:	**Hospital No:**
First name:	**Date of Birth:**
NHS No:	
Address:	

The full Shared Care Protocol can be found on the NHS Somerset Prescribing & Medicines Management intranet site

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Under the care of a hospital consultant, the patient named above has been initiated on dronedarone.
The consultant considers the patients' condition to be stable on a dose effective for arrhythmia control, and wishes the patients' GP to accept responsibility for prescribing hereafter under this shared care agreement.

Consultant actions:

1) Print this document & complete detail below.
2) Send pages 1 - 4 to GP & pages 5 & 6 to patient.
3) Initiate and prescribe at least a four week supply.

GP actions:

1) Scan pages and save in patients' record.
2) Perform four week assessment.
3) Consider continuing treatment or refer back as appropriate.
4) Complete GP declaration regarding shared care for patient & return form to specialist within 7 days.

Commencing dose of dronedarone: …….. mg Frequency ……

Hospital specialist name (print)…….. Signature……

Hospital Trust / Base…….. Telephone no: (……..…) ……

Additional comments ……...

……

Shared care agreement

The hospital specialist has undertaken all of the specialist responsibilities as described on page 3.

Consultant's declaration

I hereby declare that I, ……(specialist, please print), have undertaken all of the specialist responsibilities set out in page 3 of this shared care protocol and request the general practitioner to take on shared care responsibilities for this patient.

Signature of consultant……

The GP is asked to take on shared care for this patient under this shared care protocol.

General practitioner's declaration

I hereby declare that I, ……(GP, please print), **agree/do not agree* to take on shared care** and comply with all of the GP responsibilities set out in page 3 of this shared care protocol and will send a copy of this signed agreement back promptly to the consultant.

* delete as appropriate

Signature of general practitioner……

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Specialist responsibilities

Please tick to confirm

1. Ensure patient fulfils MHRA/CHMP (October 2011) criteria for dronedarone therapy before initiation ☐
2. Previously prescribed Class I or III antiarrhythmics are stopped before dronedarone initiated ☐
3. Liver and renal function tests performed before dronedarone initiated ☐
4. Ensure patient/carer understands what the drug is, and why it has been prescribed ☐
5. Ensure patient/carer understands how and when it should be taken, and any potential side-effects ☐
6. Ensure patient/carer understands, and can comply with, the monitoring requirements ☐
7. Prescribed at least one months' worth of dronedarone treatment ☐
8. Provide patient with completed blood form (for day 7 serum creatinine and liver function tests) and book appointment with GP ☐

General Practitioner responsibilities

1. Accept clinical responsibility for the patient provided the above criteria have been met.
2. Reinforce educational points provided by the hospital (points 4, 5 and 6 above).
3. Repeat prescribing of dronedarone no sooner than one month after initiation, and once stable.
4. Inform consultant of any changes in the patients' medical condition, especially adverse effects, and/or changes to prescribed medication.
5. Refer prescribing back to the consultant should problems arise that cannot be readily corrected.

General Practitioner monitoring responsibilities

1. Serum creatinine should be measured 7 days after treatment initiation (see initiation date above). If an increase in creatinine is observed, this value should be used as the new reference baseline. Repeat creatinine periodically thereafter. Any further increase in creatinine should lead to discontinuation of dronedarone.
2. Repeat liver function tests (LFT's) at 1 week and then at months 1, 2, 3, 4, 5, 6, 9, 12 & periodically thereafter.
3. Regular cardiac examinations, including ECG and evaluation for symptoms of heart failure **at least every 6 months.** Treatment should be discontinued in those patients who develop permanent AF.
4. Awareness of the potential for pulmonary toxicity eg. onset of dyspnoea or non-productive cough and relevant lung examinations if necessary.

Patient/carer responsibilities

1. Following counselling, to be willing to administer the dronedarone as directed at home.
2. To report signs or symptoms relating to their condition, including side effects or concordance issues to the GP.

Shared Care Protocol
Dronedarone for non-permanent atrial fibrillation

This shared care protocol (SCP) sets out details for the sharing of care for patients with non-permanent atrial fibrillation who are prescribed dronedarone. It should be read in conjunction with the Summary of Products Characteristics (SPC, available at www.emc.medicines.org.uk) and CHMP/MRHA advice (October 2011).

As outlined in NHS Circular 1992 (Gen 11), when a consultant considers a patients' condition is stable he/she may seek the agreement of the patients' GP to "share" the patients' care. This document provides information on drug treatment for the shared commitment between the consultant and GP concerned. GPs are invited to participate. If the GP is 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. The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

Introduction

Dronedarone is a multi-channel blocker, affecting potassium, sodium and calcium channels in myocytes. This prolongs the cardiac action potential and refractory period, giving it a broad anti-arrhythmic effect**.** The structure of dronedarone has several modifications compared to amiodarone, including removal of the iodine radical and the addition of a methane sulfonyl radical. This is believed to decrease the lipophilicity of dronedarone. As a result it has a shorter half life of 27-31 hours (the half life of amiodarone is of the order of 50 days). Due to safety concerns the MHRA/CHMP issued a drug safety update in October 2011.

The CHMP (Committee for Medicinal Products for Human Use) recommends that dronedarone should now only be used for the maintenance of sinus rhythm after successful cardioversion in patients with paroxysmal or persistent AF and only after alternative treatment options have been considered.
It should not be given to patients with left ventricular systolic dysfunction or to patients with current or previous episodes of heart failure.

Dronedarone (Multaq): cardiovascular, hepatic and pulmonary adverse events – new restrictions and monitoring requirements: MHRA

For further information please click on the links below or visit;

Multaq 400mg tablets - Summary of Product Characteristics (SPC) - electronic Medicines Compendium (eMC)

Contra-indications

Dose

Adverse effects

Drug interactions

Cost

BNF September, 2011

Drug	Strength	Pack size	Cost per pack	Dose	Cost per 28 days
Dronedarone	400mg	20 tablets 60 tablets	£22.50 £67.50	400mg BD	£63.00
Amiodarone	200mg	28 tablets	£1.90	200mg OD	£1.90

Shared Care Responsibilities

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to, and accepted by, the patient. This provides an opportunity to discuss drug therapy.

The clinician who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

Consultant responsibilities

- Treatment with Class I or III antiarrhythmics (such as flecainide, propafenone, quinidine, disopyramide, dofetilide, sotalol, amiodarone) must be stopped before dronedarone is initiated.
- Perform creatinine and liver function tests prior to treatment.
- Initiate treatment with dronedarone, ensuring patient/carer has a basic understanding of what the drug is, how and when it should be taken, why it is being used, and an awareness of potential side effects.
- **Complete blood form for day 7 serum creatinine and LFT's, give to patient/carer, book appointment with GP**.
- Once the consultant considers the patients' condition is stable on a dose effective for arrhythmia control, a request can be made to the patients' GP to 'share' the patients' care.
- This should be done by completing the top page of this protocol and sending pages 1-4 to the patients' GP.
- The remainder of this document should be given to the patient/carer.
- The patient/carer should be informed of arrangements for further prescriptions.
- All patients will remain under the ongoing care of a named consultant.
- The consultant will provide support if problems occur, using the contact details provided.
- The consultant will give directions as to when treatment should be discontinued.

General Practitioner responsibilities

- Accept request to take on prescribing of dronedarone once the consultant considers a patients' condition is stable and the patient is stabilized on a tolerated dose effective for arrhythmia control, no sooner than one month after initiation.
- Reinforce educational points provided by the hospital.
- **Serum creatinine should be measured 7 days after treatment initiation**. If an increase in creatinine is observed, this value should be used as the new reference baseline. Repeat creatinine periodically thereafter. Any further increase in creatinine should lead to discontinuation of dronedarone.
- **Serum LFT's should be measured 7 days after treatment initiation. Repeat liver function tests at month 1, 2, 3, 4, 5, 6, 9, 12, and periodically thereafter.**
- **Patients should receive regular cardiac examinations,** including an ECG and evaluation for symptoms of heart failure **at least every 6 months**. Treatment should be discontinued if the patient develops permanent AF.
- Awareness of the potential for pulmonary toxicity and relevant lung examinations if necessary.
- Repeat prescribing of dronedarone no sooner than one month after initiation, and once stable.
- Inform the consultant of any changes in the patient's medical condition and/or prescribed medication, especially adverse effects.
- Refer prescribing back to the consultant should problems arise that cannot be readily corrected.

Patient/carer responsibilities

- Following counselling, to be willing to administer the dronedarone as directed at home.
- To report any significant signs or symptoms relating to their condition, including side effects or concordance issues to the GP.

Further support

- Medicines Information department, Musgrove Park Hospital: 01823 342253
- Medicines Information department, Yeovil District Hospital: 01935 384327
- Prescribing & Medicines Management Team, NHS Somerset: 01935 384123

Version:	1.7	Date
Drawn up by:	Matt Brindley, Specialist Pharmaceutical Advisor, NHS Somerset	Sept 2010
Amended by:	Sarah Woolgar, Lead Pharmacist Cardiology	Nov 2011
Approved by:	Somerset Prescribing Forum, NHS Somerset	November 2011
	Drug & Therapeutics Committee, Taunton & Somerset NHS FT	
	Drug & Therapeutics Committee, East Somerset NHS FT	
	Drug & Therapeutics Committee, Somerset Partnership NHS FT	N/A
Review required by:		March 2014

References:

- NICE TA197 - Dronedarone for the treatment of non-permanent atrial fibrillation, August 2010
- Summary of Product Characteristics, Multaq 400mg tablets, Sanofi Aventis, March 2010
- Drug Safety Update MHRA October 2011