Review Date: November 2019

# EFFECTIVE SHARED CARE AGREEMENT OF DRONEDARONE (MULTAQ®) FOR THE MAINTENANCE OF SINUS RHYTHM AFTER SUCCESSFUL CARDIOVERSION IN ADULT CLINICALLY STABLE PATIENTS WITH PAROXYSMAL OR PERSISTENT FIBRILLATION (AF)

#### **RESPONSIBILITIES and ROLES**

# Specialist responsibilities

- Discuss the benefits and side effects of treatment with the patient.
- 2 Check for possible drug interactions with dronedarone and the patient's regular medication and avoid prescribing interacting drugs.
- Assess likelihood of compliance. 3
- Ensure patient is given sufficient information about their treatment. 4
- Perform liver function tests (LFTs) before initiating treatment with dronedarone and during treatment as per 5 MHRA/SPC advice.
- Measure plasma creatinine values prior to and 7 days after initiation of dronedarone. 6
- Perform ECGs serially, at baseline, month 1, month 6, month 12 and every 6 months thereafter. 7
- Initiate and stabilise treatment with dronedarone according to its licensed indications. 8
- Prescribe dronedarone until care is transferred to GP. 9
- 10 Ask the GP whether he or she is willing to participate in shared care and explain the intention to share care with patient/carer and obtain consent.
- Monitor appropriately as stated on the monitoring requirement. 11
- Inform GP of the dose to be prescribed, any changes in dose, when to stop treatment and when to refer the patient 12 back to specialist.
- Ensure GP has access to blood results for information. 13
- Monitor for side effects and report adverse events to the MHRA and GP where appropriate. 14
- Inform GP if patient does not attend specialist appointments and action to be taken. 15
- Have a mechanism in place to receive rapid referral of a patient from the GP in event of deteriorating clinical 16 condition.
- Ensure that clear backup arrangements exist for GPs to obtain advice and support. 17

#### **General Practitioner responsibilities**

- Reply to the request for shared care as soon as possible. 1
- Prescribe dronedarone at the dose recommended once patient is established on treatment. 2
- Ensure compatibility with other concomitant medication. 3
- Adjust the dose as advised by the specialist. 4
- Contact the specialist if you suspect the patient is not complying with their medication. 5
- Check for possible drug interaction when prescribing new medication and avoid prescribing interacting drugs. 6
- Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises. 7
- Refer the patient to the specialist if his/her condition deteriorates. 8
- Report any suspected adverse events to specialist team and any severe adverse events to MHRA.

#### Patient's / Carer's role

- Take dronedarone as recommended by specialist. 1
- Report to the specialist or GP if he/she does not have a clear understanding of the treatment. 2
- Request repeat prescriptions from the GP at least 5 days before the next supply is needed. 3
- 4 Attend scheduled appointments with specialist, GP and for monitoring.
- Share any concerns in relation to treatment with GP or specialist. 5
- Inform specialist or GP of any other medication being taken, including over-the-counter products 6
- Inform specialist or GP if you feel you are having problems taking your medication or have stopped taking it. 7
- Report any adverse effects to the specialist or GP. Patients should immediately report any symptoms of heart 8 failure (such as weight gain, swollen ankles, or breathing difficulties), or liver injury (including sustained new-onset abdominal pain, loss of appetite, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine or itching), or respiratory disorders (shortness of breath or non-productive cough) to the specialist or GP.

Written by (clinician): Dr Thanh T Phan Written by (pharmacist): Andrew Murray Version number: 3

Approved by North Staffordshire & Stoke-on-Trent Area Prescribing Committee (date): 25/10/17

## SUPPORTING INFORMATION EFFECTIVE SHARED CARE AGREEMENT

Information on therapeutic indication, dosage, method of administration, side effects and management considerations in special populations can be found in the Summary of Product Characteristics for dronedarone (Multaq®) available from www.medicines.org.uk

Monitoring requirements

Monitoring Interval	ECG (Identify reversion to AF and measure QTc)	LFTs	Creatinine	GP or Consultant
Baseline	✓	✓	✓	Consultant
Week 1		✓	✓	Consultant
Month 1	✓	✓		Consultant
Month 2		✓		Consultant
Month 3		✓		Consultant
Month 4		✓		Consultant
Month 5		✓		Consultant
Month 6	✓	✓		Consultant
Month 9		✓		Consultant
Month 12	<b>√</b>	✓		Consultant
very 6 months thereafter	✓	✓		Consultant

**Primary Care Cost** 

Product	Pack size	Cost per OP*
Dronadarone 400mg tablets	20	£22.50

<sup>\*</sup>Cost from online October 2017 Drug Tariff

## **BACK-UP ADVICE AND SUPPORT**

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