

SHARED CARE ARRANGEMENT AND PRESCRIBING INFORMATION FOR DRONEDARONE (adults only)

Note: This document should be read in conjunction with the current Summary of Product Characteristics (SmPC).

Patient safety is paramount. The clinician who signs the prescription legally assumes clinical responsibility for the medicine and the consequences of its use.

GENERIC NAME (formulation and strength)

Name: Dronedarone (as hydrochloride)

Formulation: film-coated tablets

Strength: 400mg

STATUS OF MEDICINE

Licence status: POM; licensed for requested condition.

Formulary status: Amber 1 - Treatment may be initiated in Primary Care on the recommendation of a consultant/specialist

Black triangle medicine: No

Risk minimisation materials (RMM): Yes

<https://www.medicines.org.uk/emc/product/497/rmms>

CONDITION(S) TO BE TREATED

Dronedarone is licensed for the maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation (AF).

Due to its safety profile dronedarone should only be prescribed after alternative treatment options have been considered.

TYPICAL DOSAGE REGIME

Licensed dose	The recommended dose is 400mg twice daily in adults. It should be taken as one tablet with the morning meal and one tablet with the evening meal. If a dose is missed, patients should take the next dose at the regular scheduled time and should not double the dose.
Route of administration	Oral. Tablets should not be split/halved and should be swallowed whole with a drink of water during a meal.
Recommended starting dose	As directed by specialist
Titration dose/increment	N/A
Maximum dose	400mg twice daily
Situations requiring dose adjustment	See Table 1
Duration of treatment	As directed by specialist. Note: Not recommended to be continued if the patient develops permanent AF with a duration of >6 months.

RESPONSIBILITY OF ACUTE CARE/SPECIALIST SERVICE

Also see Multaq® Prescriber Guide (prescriber guides also available for individual generic products via www.medicines.org.uk)
<https://www.medicines.org.uk/emc/product/497/rmms#about-medicine>

Undertake baseline investigations/monitoring and initiate treatment.

- Baseline monitoring:
 - Urea and Electrolytes (U&Es) and Liver Function Tests (LFTs)
 - ECG
- Confirm absence of contraindications or significant drug interactions, and assess risk/benefit of treatment.
- Copy of baseline results to be sent to primary care clinician/continuing prescriber.
- Request for initiation of therapy to Primary Care.
- Ensuring the patient is aware of required monitoring and side effects to report.
- Monitor the condition, response to the treatment and need to continue. Advise the GP of the need to discontinue treatment and how (if necessary).
- Advise patient not to take St. John's Wort and avoid grapefruit juice.
- Advise the patient to contact a healthcare professional immediately if they experience any signs/symptoms of potential liver injury (such as new onset abdominal pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine or itching) or of new cardiac or pulmonary symptoms or signs (such as weight gain, dependent oedema or increased dyspnoea).
- Inform the GP of patients who fail to attend clinic review appointments.
- Counsel female patients, where appropriate, of pregnancy and ensure taking adequate contraceptive precautions during treatment and for one month after discontinuation.
- Be available for advice if the patient presents to the GP with new cardiac or pulmonary symptoms or signs, signs of hepatic impairment or reverts back to AF.
- Review the patient regularly in clinic. If the patient has reverted back to AF, consideration should be given to stopping the treatment, and treatment should be stopped if permanent atrial fibrillation occurs.
- Report any adverse effects detected to the MHRA using the Yellow Card System and GP (as necessary).

RESPONSIBILITIES OF PRIMARY CARE/PRESCRIBING CLINICIAN

Also see Multaq® Prescriber Guide (or other relevant information related to generic products available via www.medicines.org.uk)
<https://www.medicines.org.uk/emc/product/497/rmms#about-medicine>

A practice/prescriber agreeing to prescribe dronedarone should:

- Prescribe medication under the guidance of the Consultant from the specialist service. Checking before prescribing each instalment of medication that the monitoring is up to date and results are within a satisfactory range (refer to [Table 1](#) for actions).
- Primary Care may advise patients to start dronedarone 7 days prior to their first scheduled CTAC monitoring appointment to ensure blood testing at the required frequency after initiation.
- Ensure that the relevant monitoring requirements are undertaken at the correct frequency.

- The Practice/General Practitioner (GP) has primary responsibility for monitoring and timely review of results. Refer to monitoring section.
- When completing laboratory requests always include details of the patient's medication.
- Only continue to prescribe medication if it is being satisfactorily monitored.
- Ensure that the test results are checked for any abnormality as soon as the results are available.
- Ensure abnormal results are acted upon promptly (see Common Side Effects and Their Management).
- Contact acute care/specialist in the event of a drug reaction, monitoring abnormality, or if you are concerned in any way regarding the current treatment regime.
- Contact acute care/specialist service for advice regarding any signs/symptoms which suggest toxicity or cause concern, if AF recurs or permanent AF develops.
- Ensure no interacting medications are prescribed in primary care (See SmPC for full details).
- Monitor for concordance with therapy.
- Remind patient of signs and symptoms to report.
- Report any adverse events to consultant and the MHRA using the Yellow Card System.

If something unexpected occurs contact consultant. Notify the consultant if the drug is stopped.

MONITORING

Primary Care is responsible for ongoing monitoring.

Primary Care may advise patients to start dronedarone 7 days prior to their first scheduled CTAC monitoring appointment to ensure blood testing at the required frequency after initiation.

- Liver Function Tests (LFTs) at 7 days, 1 month, monthly for 6 months, and at 9 and 12 months post initiation.
LFTs should then be monitored annually unless there are concerns or slightly raised levels, where 3 monthly monitoring is recommended. Continued monitoring of LFTs and close observation of patients may be required if treatment requires to be stopped until LFTs normalise.
- Creatinine at day 7, with a recheck at day 14 if a raised creatinine levels is seen on day 7. Consideration should be made for discontinuation if creatinine continues to rise and should be discussed with the acute care/specialist service.
Creatinine should be monitored periodically, suggested at least 6 monthly, thereafter.
- Evaluate the patient at least every 6 months including ECG and evaluation of symptoms of heart failure, liver and pulmonary toxicity.

Note: In addition to absolute values for haematological or biochemical indices a rapid change or a consistent upward/downward trend in any value should prompt caution and extra vigilance.

RESPONSIBILITY OF THE PATIENT

- Take medication regularly as directed by the specialist/doctor.
- Attend hospital and GP clinic appointments as requested by specialist/GP practice.
Failure to attend appointments may result in medication being reviewed/stopped.

- Report any adverse effects/illness to the specialist/GP and present rapidly to specialist/GP should their condition significantly worsen.
- Avoid St John's Wort and grapefruit juice whilst taking dronedarone.

PRESCRIBING INFORMATION

For specific product information consult the current Summary of Product Characteristics (<http://emc.medicines.org.uk/>), the BNF (<https://www.medicinescomplete.com/mc/index.htm>)

Also see Multaq® Prescriber Guide (or other relevant information related to generic products available via www.medicines.org.uk)
<https://www.medicines.org.uk/emc/product/497/rmms#about-medicine>

CONTRAINDICATIONS

- Left ventricular systolic dysfunction or patients with current or previous episodes of heart failure.
- Permanent AF (duration >6 months or unknown) and attempts to restore sinus rhythm no longer considered.
- Severe renal (CrCl<30mL/min) or liver impairment.
- Liver or lung toxicity related to previous amiodarone use.
- 2nd or 3rd degree atrioventricular (AV) block, complete bundle branch block, distal block, sinus node dysfunction, conduction defects or sick sinus syndrome (unless permanent pacemaker in situ).
- Bradycardia (<50bpm).
- Co-administration of potent CYP450 inhibitors such as ketoconazole, itraconazole, voriconazole, posaconazole, telithromycin, clarithromycin, nefasazone and ritonavir.
- Co-administration with other medicine which may induce torsades de pointes such as phenothiazines, tricyclic antidepressants, terfenadine, oral macrolides, Class I and III antiarrhythmics.
- Co-administration with dabigatran (also see interaction section for DOACs).
- Potassium and magnesium deficiency.
- QTc >500milliseconds.
- Hypersensitivity to active substance or excipients.

PREGNANCY

Not recommended. Adequate contraception is required during and for one month after stopping treatment.

BREAST-FEEDING

Not known. Advise to avoid.

COMMON SIDE EFFECTS AND THEIR MANAGEMENT

The most common adverse events include diarrhoea, nausea, vomiting, fatigue and asthenia. Congestive heart failure, LFT abnormalities, increase in creatinine and QTc (as detailed above), dyspepsia, rashes, pruritus and bradycardia are also commonly seen. See SmPC for full list.

Table 1: Abnormal monitoring results

Abnormal Monitoring Results	Action To Be Taken
ALT ≥ 3 times upper limit of normal on a single blood test	Repeat blood test within 48 to 72 hours.
ALT ≥ 3 times upper limit of normal on 2 tests, taken within 48 to 72 hours of each other	Contact acute care/specialist service urgently to inform of need for treatment withdrawal, and arrange any appropriate investigations.
Symptoms of dyspnoea or non-productive cough	Contact acute care/specialist service urgently for relevant lung examinations for suspected pulmonary toxicity and inform of need to withdraw treatment.
Symptoms and signs of heart failure	Contact acute care/specialist service urgently for investigation and inform of need to withdraw treatment.
Continued increase in creatinine	Refer to acute care/specialist service for consideration of withdrawal of treatment. Discuss urgently if CrCl < 30 mL/min.
Recurrence of AF or development of permanent AF > 6 months	Refer to acute care/specialist service for consideration of withdrawal of treatment.
QTc ≥ 500 milliseconds	Contact acute care/specialist service urgently to inform of need for treatment withdrawal.
Heart rate < 50 bpm	Refer to acute care/specialist service and review concurrent medications as appropriate.
Low potassium or magnesium	Correct with supplementation and review concurrent medication for causes as appropriate as abnormal electrolytes have implications for rhythm control. Note: Magnesium should be checked if other electrolyte abnormalities are detected, or if the clinical condition of the patient requires, and corrected as appropriate.

COMMON DRUG INTERACTIONS (for a full list see SmPC)

Also see Multaq® Prescriber Guide (or other relevant generic brand via www.medicines.org.uk) <https://www.medicines.org.uk/emc/product/497/rmms#about-medicine>
Please also refer to Contraindications (above).

- Grapefruit juice: Patient should be advised to avoid grapefruit juice.
- Digoxin: Dose should be halved with concurrent dronedarone prescription. Clinical, ECG and biological monitoring is recommended for this combination.
- Statins: Should be used with caution, and lower starting and maintenance doses be considered, monitoring closely for signs of muscle toxicity.
- Warfarin: INR should be monitored closely. INR may increase significantly within one week after starting dronedarone.
- Rivaroxaban: Due to lack of clinical data, co-prescribing is advised to be avoided by UK rivaroxaban manufacturer. All other DOACs are advised to only be used with caution.

- Edoxaban: Ensure appropriate dose reduction as per manufacturer's instructions.
- Potent CYP3A4 inducers such as rifampicin, phenobarbital, carbamazepine, phenytoin or St John's Wort are not recommended.
- MAO inhibitors might decrease the clearance of the active metabolite of dronedarone and should therefore be used with caution.
- Dronedarone could increase plasma concentrations of immunosuppressants (tacrolimus, sirolimus, everolimus and cyclosporine). Plasma serum concentration monitoring is recommended.
- Other sinus node or AV node depressants (e.g. beta blockers, rate limiting calcium antagonists) may predispose to bradycardia.
- Erythromycin: Due to the risk of inducing Torsades de Pointes.
- Dabigatran (see contraindications).
- Beta blockers: Sotalol must be stopped before starting dronedarone. Beta blocker metabolised by CYP 2D6 (e.g. metoprolol and propranolol) will have their exposure increased by dronedarone, thus carry an increased risk of excessive bradycardia.

If an adverse reaction does occur inform relevant medical practitioner as soon as possible.

Report to the MHRA using the Yellow Card System <https://yellowcard.mhra.gov.uk/>

REFERENCES

Electronic Medicines Compendium (eMC), 2014. Multaq 400mg tablets. [Online]
Available at: <https://www.medicines.org.uk/emc/product/497/smpc>
[Last updated 01 January 2021; Accessed December 2024].

ACUTE CARE/SPECIALIST SERVICE CONTACT INFORMATION

In the event of concern being raised, the primary care practitioner should contact the referring consultant via the hospital switchboard, via their secretary, by e-mail or letter, whichever is more appropriate. If the concern is urgent, and out of hours advice is required, the on call cardiologist may be contacted via switchboard.

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