Highland Formulary
Dronedarone treatment protocol

Drug
Dronedarone 400mg tablets (Multaq®)
Indication
Maintenance of sinus rhythm in adult clinically stable patients with paroxysmal atrial fibrillation or persistent atrial fibrillation after cardioversion. Treatment will be initiated in patients without heart failure after other drugs have been considered.
Dosage
400mg twice daily, with morning and evening meals.
Initiation and maintenance of treatment – delineation of responsibilities

Initiation - Treatment will be initiated by a consultant cardiologist

Before treatment is started, the consultant will record an ECG and serum creatinine, potassium and magnesium, and LFTs.

Treatment with Class I or III antiarrhythmics (such as flecainide, propafenone, quinidine, disopyramide, dofetilide, sotalol, amiodarone) will be stopped before starting dronedarone.

The consultant is responsible for ensuring that there are no contra-indications or clinically significant drug interactions when treatment with dronedarone is started.

The consultant will inform the patient of the monitoring that the GP will carry out and of any symptoms that should be reported to the GP (see below).

Continuation of treatment - GP's responsibilities

Measure LFTs

- monthly for the first 6 months of treatment
- then at months 9 and 12
- every 6 months thereafter.

If alanine transaminase (ALT) levels are elevated to ≥ 3 times upper limit of normal (ULN), retest within 48 to72 hours. If ALT levels are confirmed to be ≥ 3 times ULN after retesting, withdraw dronedarone treatment.

As previously advised by the consultant, the GP will advise patients to report any of the following symptoms immediately:

- symptoms of potential liver injury such as sustained new onset abdominal pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine or itching
- symptoms of heart failure such as weight gain, dependent oedema or increased dyspnoea.

Note that dronedarone is a newly licensed medicine under intense monitoring by the MHRA. All suspected adverse reactions to dronedarone should be reported to the MHRA via the Yellow Card Scheme at www.yellowcard.gov.uk.

Drug interactions

Dronedarone has many important potential drug interactions. These will be considered when treatment is initiated. No medicine should be added to or withdrawn without consulting with Appendix 1 of the BNF, the Summary of Product Characteristics and, if necessary, the cardiologist.

Of particular note are interactions with:

- a variety of cardiovascular medicines, eg anti-arrhythmics, beta-blockers, calcium-channel blockers, statins, digoxin, dabigatran
- antibacterials, eg clarithromycin, erythromycin, rifampicin
- anti-epileptics, eg carbamazepine, phenytoin
- antipsychotics
- tricyclic antidepressants and St John's Wort
- grapefruit juice.

Advice to patients

- do not take grapefruit juice
- do not take St John's Wort
- if a dose is missed, take the next dose at the regular scheduled time; do not double the dose
- changes listed above should be reported to the GP.

References

Summary of Product Characteristics, available at http://www.medicines.org.uk/EMC/medicine/22894/SPC/Multaq+400mg+tablets/

British National Formulary 61 (March 2011)

'Dronedarone (Multaq▼): cardiovascular, hepatic and pulmonary adverse events – new restrictions and monitoring requirements' MHRA Update, October 2011, available at http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con131944.pdf