MULTAQ® (dronedarone) PRESCRIBER GUIDE

This guide contains important safety information for the safe use of dronedarone.

Aim of this Guide:

To provide dronedarone prescribers with a guide to:

1. Screen patients before treatment initiation
2. Monitor patients during treatment
3. Discontinue dronedarone when required
4. Counsel patients about its use

This is additional to the Summary of Product Characteristics (SmPC) and Patient Information Leaflet. Thus, it does not include the full prescribing information.

Safe Use:

- Treatment with dronedarone should only be:
  - Initiated and monitored under specialist supervision
  - Prescribed after alternative treatment options have been considered
- Treatment with dronedarone can be initiated in an outpatient setting.

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BEFORE TREATMENT INITIATION

If **any** of the 'Yes' criteria **(Red Buttons)** apply, do not prescribe dronedarone. You should only prescribe Dronedarone if **all** 'No' criteria **(Green Buttons)** apply. Contraindications should be confirmed by **ECG, serum creatinine and, liver and pulmonary tests**.

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

If any red 'Yes' applies do not initiate dronedarone

Atrial Fibrillation

- Yes — Hypersensitivity to the active substance or to any of the excipients.
- No
- Yes — **Permanent AF with an AF duration ≥6 months (or duration unknown) and attempts to restore sinus rhythm no longer considered by the physician**
- No

Heart Failure

- Yes — Second- or third- degree atrio-ventricular block, complete bundle branch block, distal block, sinus node dysfunction, atrial conduction defects or sick sinus syndrome (except when used in conjunction with a functioning pacemaker).
- Yes — QTc Bazett interval ≥ 500 milliseconds.)
- Yes — **History of, or current heart failure or left ventricular systolic dysfunction (LVSD)**
- Yes — Unstable hemodynamic conditions
- Yes — Pre-renal azotaemia (functional impairment)
- Yes — Bradycardia <50 beats per minute (bpm)
- No

Drug – Drug Interactions

- Yes — Potential torsades de pointes inducers *(phenothiazines, cisapride, bepridil, tricyclic antidepressants, terfenadine and certain oral macrolides)*
- Yes — Potent cytochrome P 450 (CYP) 3A4 inhibitors *(ketoconazole, itraconazole, voriconazole, posaconazole, telithromycin, clarithromycin, nefazodone and ritonavir)*
- Yes — Class I or Class III antiarrhythmics
- Yes — Dabigatran
- No

Liver & Lung

- Yes — Severe hepatic impairment
- Yes — Liver and lung toxicity related to the previous use of amiodarone
- No

Kidney

- Yes — Severe renal impairment (CrCl <30 ml/min)
- No

Dronedarone can be initiated

MONITORING DURING TREATMENT

The following assessments are recommended during treatment with dronedarone. Criteria for discontinuation are also described. If **any** of the 'Yes' criteria **(Red Buttons)** arise during treatment, dronedarone should be discontinued.

ECG:
Serially, at least every 6 months

Patient develops permanent AF — Yes

SYMPTOMS OF:
- Heart failure
- LVSD (monitoring of left ventricular function)

Patient develops heart failure or LVSD — Yes

USE WITH CAUTION *(in association with):*
- Digitalis
- Beta blockers, calcium antagonists with heart rate lowering properties, statins
- Drug modifying INR (warfarin)
- Sirolimus and tacrolimus

NOT RECOMMENDED *(in association with):*
Grapefruit juice, potent CYP3A4 inducers including rifampicin, phenobarbital, carbamazepine, phenytoin, St John's Wort

LIVER FUNCTION TESTS:
After 1 week → after 1 month → monthly for 6 months → at months 9 and 12 → periodically

ALT levels are confirmed to be ≥3 ULN — Yes

PULMONARY FUNCTION TESTS

Pulmonary toxicity — Yes

SERUM CREATININE*: After 1 week → after a further 7 days if ↑ creatinine

Serum creatinine continues to ↑ — Yes

If any red 'Yes' applies dronedarone must be discontinued

**Plasma creatinine levels may rise initially due to inhibition of renal tubular excretion of creatinine and are not necessarily indicative of a deterioration in renal function*

PATIENT COUNSELLING

Patients should be informed that during treatment with dronedarone **blood tests and ECGs** will be performed, and should be advised on the following:

To consult a physician if they develop: *palpitations, sensation of rapid or irregular heart beats*

To consult a physician if they develop: *weight gain, dependent oedema, increased dyspnoea*

Dronedarone interacts with a number of medicines:
- **To inform any other doctor** that they are under treatment with dronedarone
- They **should not take** St. John's Wort
- They should **avoid** grapefruit juice

To report immediately if they develop: *new-onset abdominal pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine or itching*
To consult a physician if they develop: *non-productive cough, breathlessness*

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via contacting HPRA Pharmacovigilance, website: www.hpra.ie.
Side effects should also be reported to Sanofi: Tel: 01 403 5600 e-mail: IEPharmacovigilance@sanofi.com