

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.

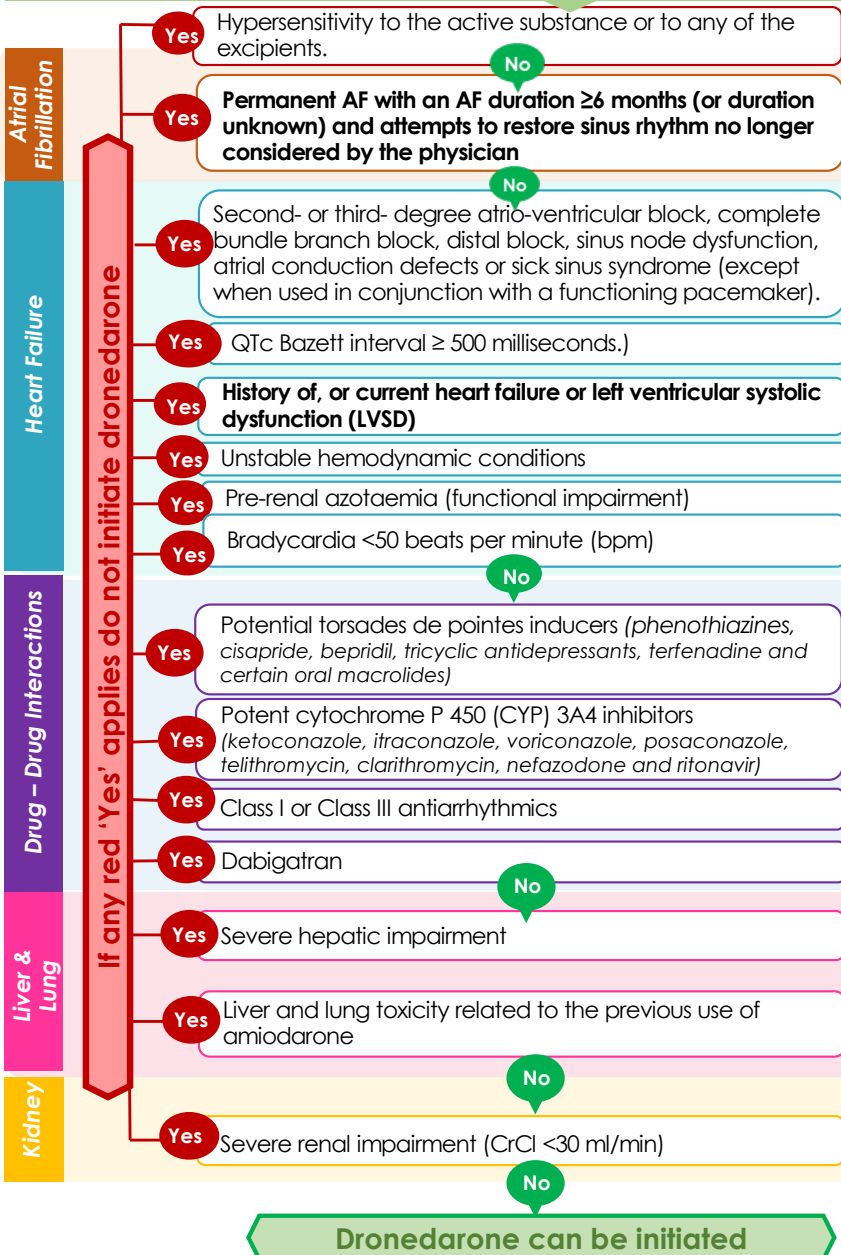
Safe Use:

- 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.

BEFORE TREATMENT INITIATION

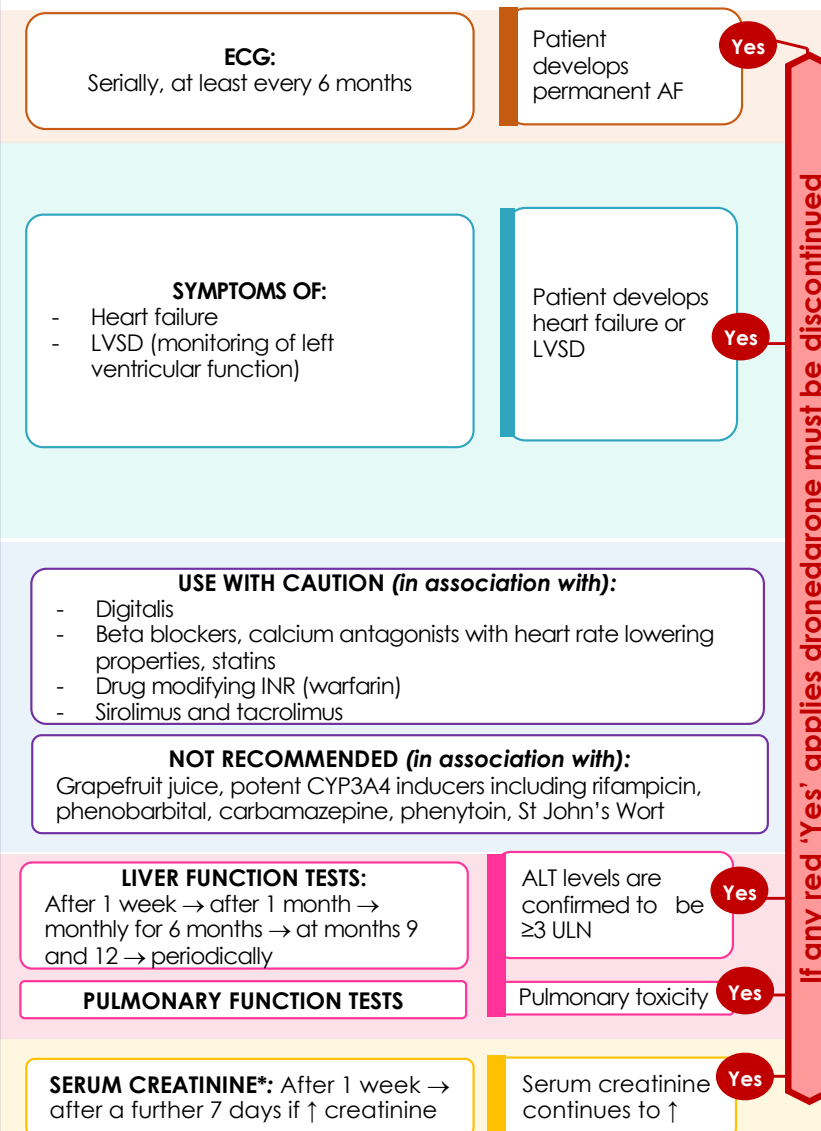
If **any** of the 'Yes' criteria (**Red Buttons**) apply, do not prescribe dronedarone. You should only prescribe Dronedarone if **all** 'No' criteria (**Green Buttons**) apply. Contraindications should be confirmed by **ECG, serum creatinine and, liver and pulmonary tests**.

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



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.



*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