

MULTAQ[®] PRESCRIBER GUIDE

This guide contains important safety information for the safe use of dronedarone (Multaq[®])

Aim of this Guide:

To provide Multaq[®] (dronedarone) prescribers with a guide to:

1. Screen patients before treatment initiation
2. Monitor patients during treatment
3. Discontinue Multaq[®] 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 Multaq[®] should only be:
 - Initiated and monitored under specialist supervision
 - Prescribed after alternative treatment options have been considered
- Treatment with Multaq[®] can be initiated in an outpatient setting.

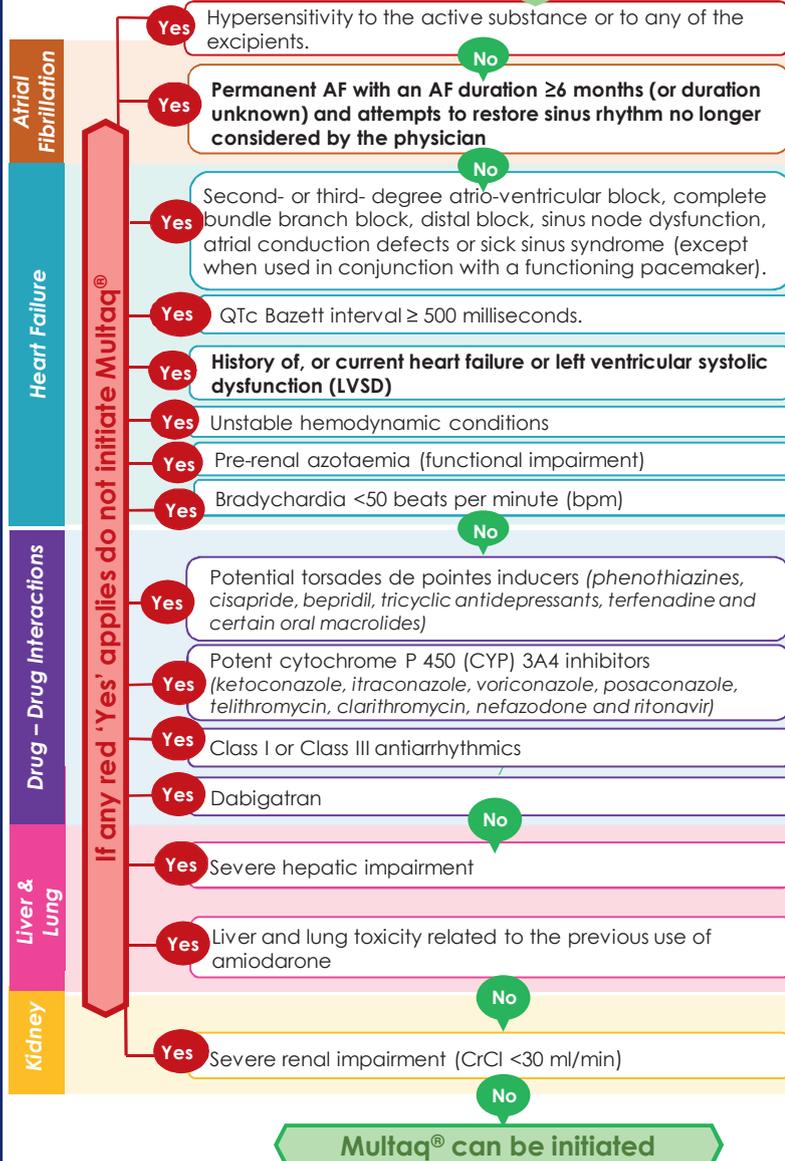
Call for Reporting

Healthcare professionals are encouraged to report all the adverse events suspected to be associated with the use of Multaq[®] to the Medicines Authority. Report Form can be downloaded from <http://www.medicinesauthority.gov.mt/adrportal> and sent to Post-licensing Directorate, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000 Malta, or by email to postlicensing.medicinesauthority@gov.mt. Alternatively any suspected adverse reactions and medication error can be reported to Sanofi Spa, Viale Luigi Bodio, 37/b - 20158 Milano, Italy at PharmacovigilanceMalta@sanofi.com

BEFORE TREATMENT INITIATION

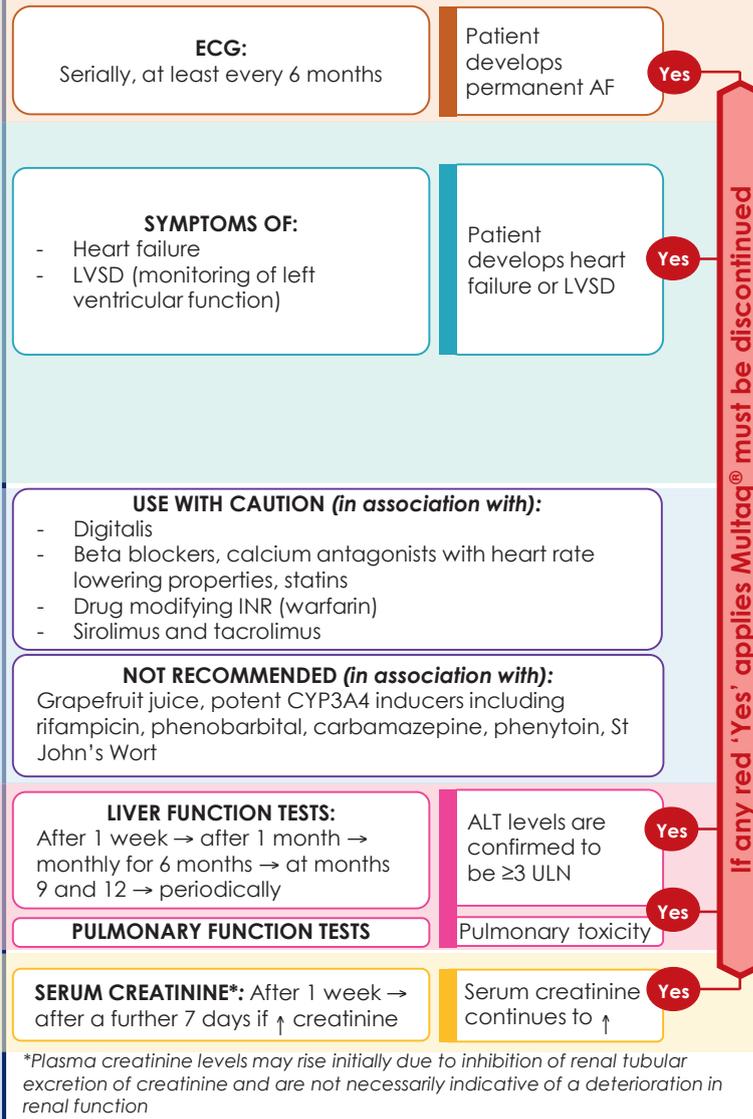
If **any** of the 'Yes' criteria (**Red Buttons**) apply, do not prescribe Multaq®. You should only prescribe Multaq® if **all** 'No' criteria (**Green Buttons**) apply. Contraindications should be confirmed by **ECG, serum creatinine and, liver and pulmonary tests.**

Multaq® 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 Multaq®. Criteria for discontinuation are also described. If **any** of the 'Yes' criteria (**Red Buttons**) arise during treatment, Multaq® should be discontinued.



PATIENT COUNSELLING

Patients should be informed that during treatment with Multaq® **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

Multaq® interacts with a number of medicines:

- **To inform any other doctor** that they are under treatment with Multaq®
- 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 drug reactions** is important for continued monitoring of the benefit/risk balance. Healthcare professionals are asked to report any suspected adverse reactions to **Medicines Authority** at postlicensing.medicinesauthority@gov.mt or to **Sanofi Spa** at PharmacovigilanceMalta@sanofi.com