

# MULTAQ<sup>®</sup> (Dronedarone) PRESCRIBER GUIDE

*This guide contains important safety information for the safe use of dronedarone (Multaq<sup>®</sup>)*

**Aim of this Guide:** To provide Multaq<sup>®</sup> (dronedarone) prescribers with a guide to:

1. Screen patients before treatment initiation
2. Monitor patients during treatment
3. Discontinue Multaq<sup>®</sup> 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<sup>®</sup> should only be:
  - Initiated and monitored under specialist supervision
  - Prescribed after alternative treatment options have been considered
- Treatment with Multaq<sup>®</sup> 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<sup>®</sup> 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](mailto:postlicensing.medicinesauthority@gov.mt) or using the link

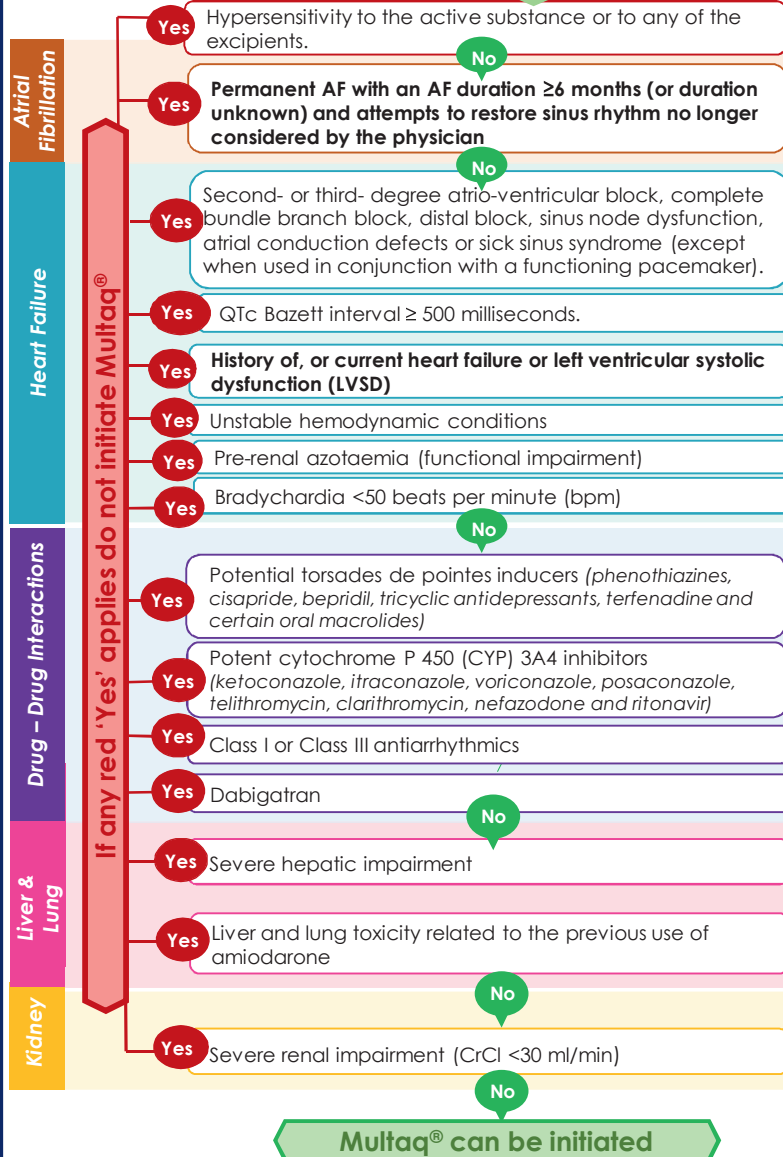
<https://medicinesauthority.gov.mt/adversedrugreactions?l=1>

Alternatively any suspected adverse reactions and medication error can be reported to Sanofi Srl, Viale Luigi Bodio, 37/b - 20158 Milano, Italy at [PharmacovigilanceMalta@sanofi.com](mailto:PharmacovigilanceMalta@sanofi.com)

## BEFORE TREATMENT INITIATION

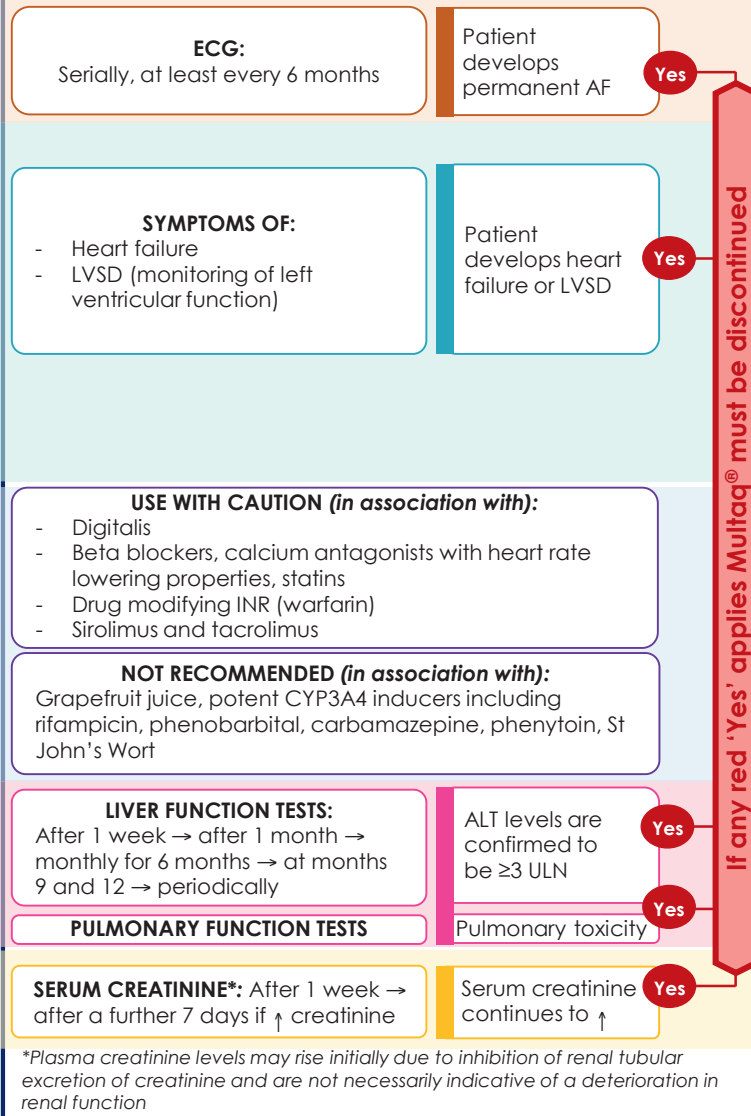
If **any** of the 'Yes' criteria (**Red Buttons**) apply, do not prescribe Multaq®. You should only prescribe Multaq® if **all** 'No' criteria (**Green Buttons**) apply. Contraindications should be confirmed by **ECG, serum creatinine and, liver and pulmonary tests.**

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](mailto:postlicensing.medicinesauthority@gov.mt) or to **Sanofi** Srl at [PharmacovigilanceMalta@sanofi.com](mailto:PharmacovigilanceMalta@sanofi.com)