

MULTAQ[®] (Dronedarone) 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 or using the link

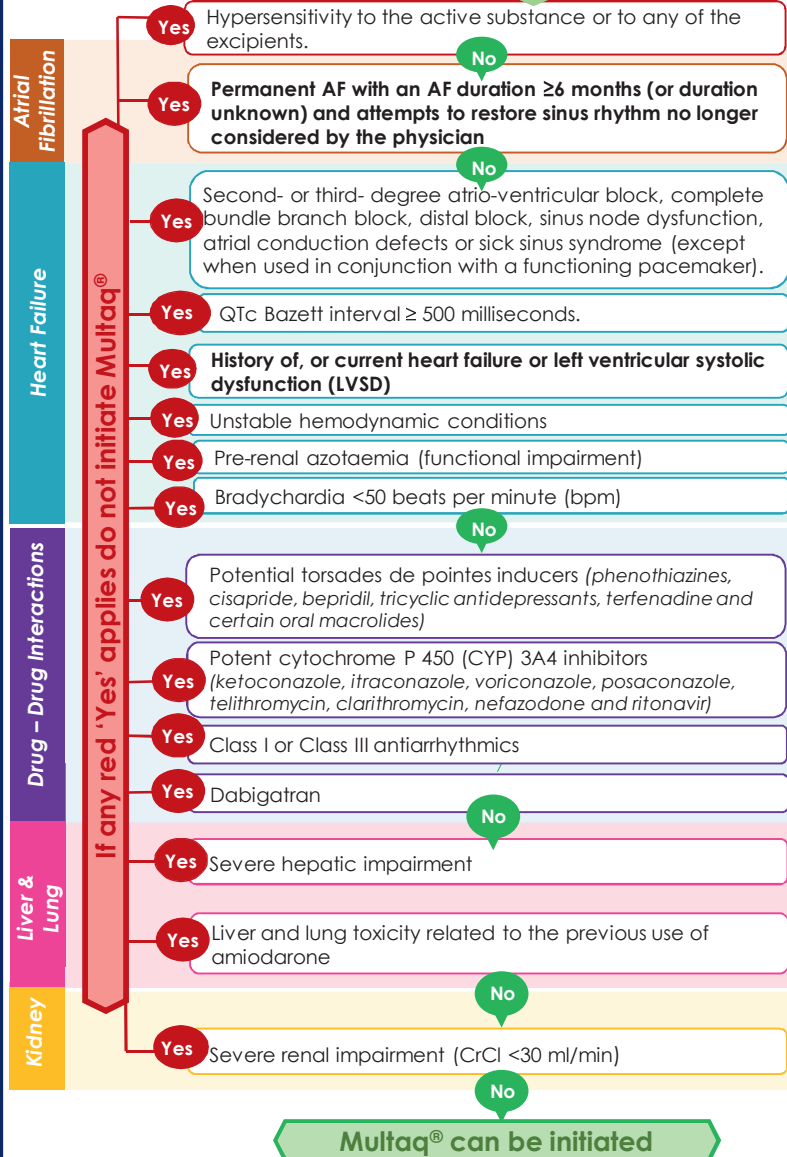
<https://medicinesauthority.gov.mt/adversedrugreactions?l=1>

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

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.**

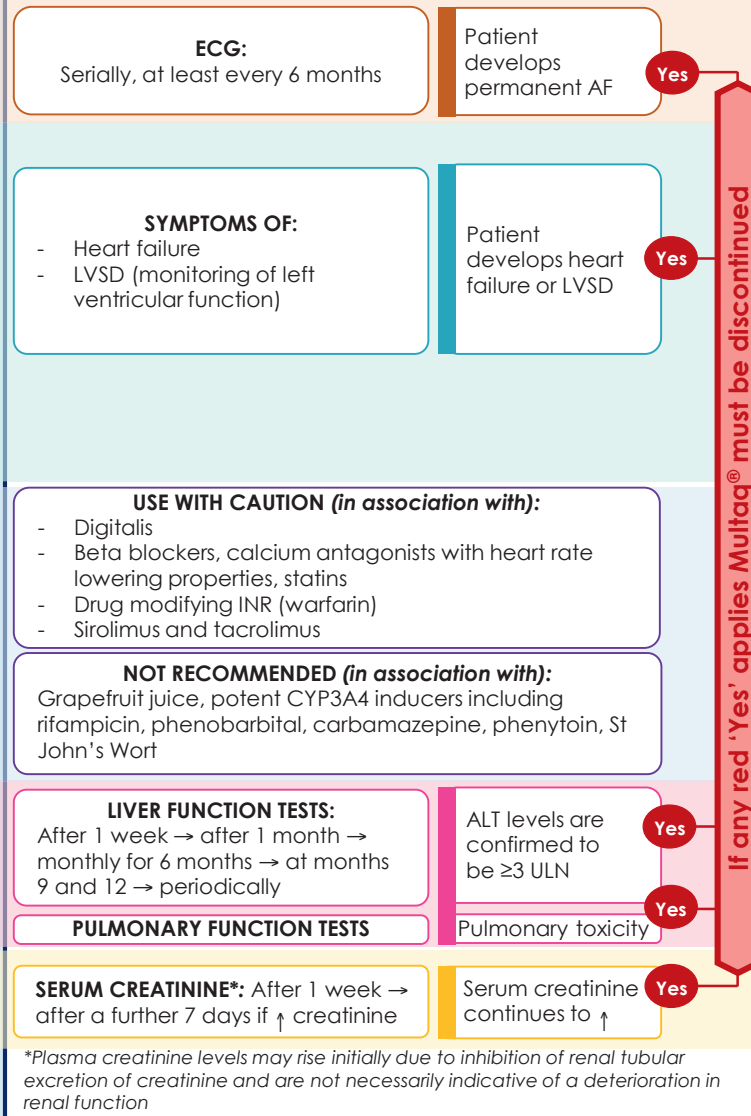
Multaq® is **indicated** for the maintenance of sinus rhythm after successful cardioversion in clinically stable adult patients with paroxysmal or persistent atrial fibrillation (AF)



Multaq® can be initiated

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.



*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 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** Srl at PharmacovigilanceMalta@sanofi.com