MULTAQ® (Dronedarone) Prescriber Checklist

|Version dated 12 August 2012|

This checklist can assist you when prescribing MULTAQ®. Treatment with MULTAQ® should be initiated and monitored only under specialist supervision. Treatment with MULTAQ® can be initiated in an outpatient setting. See the SPC for full prescribing information.

MULTAQ® is indicated for the maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation (AF). Due to its safety profile (see sections 4.3 and 4.4), MULTAQ® should only be prescribed after alternative treatment options have been considered. MULTAQ® should not be given to patients with left ventricular systolic dysfunction or to patients with current or previous episodes of heart failure.

There is limited information on the optimal timing to switch from amiodarone to MULTAQ®. Amiodarone may have a long duration of action after discontinuation due to its long half life.

If any of the criteria below is checked **YES**, do not prescribe MULTAQ®.

Medical Conditions	YES	NO
- The patient has hypersensitivity to the active substance or to any of the excipients.	☐	☐
- The patient has 2nd or 3rd 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).	☐	☐
- The patient has bradycardia (<50 beats per minute).	☐	☐
- The patient has permanent AF with an AF duration ≥ 6 months (or duration unknown) and attempts to restore sinus rhythm no longer considered by the physician.	☐	☐
- The patient has a history of, or current heart failure or left ventricular systolic dysfunction.	☐	☐
- The patient has severe hepatic impairment.	☐	☐
- The patient has severe renal impairment (CrCl <30ml/min).	☐	☐
- The patient has experienced liver or lung toxicity related to the previous use of amiodarone.	☐	☐
- The patient has a QTc Bazett interval ≥500 milliseconds.	☐	☐
Concomitant Medications		
- The patient is currently being treated with potent cytochrome P450 (CYP) 3A4 inhibitors (e.g. ketoconazole, itraconazole, voriconazole, posaconazole, telithromycin, clarithromycin, nefazodone and ritonavir)	☐	☐
- The patient is using medicinal products inducing torsades de pointes (e.g. phenothiazines, cisapride, bepridil, tricyclic antidepressants, terfenadine and certain oral macrolides [such as erythromycin], Class I and III antiarrhythmics)	☐	☐
- The patient is currently being treated with Dabigatran	☐	☐

The following main assessments are recommended before starting and during MULTAQ® therapy.

Assessments at initiation of MULTAQ

☐	ECG	☐	Digoxin, beta blockers, calcium antagonists, statins
☐	LVEF, CHF status	☐	Anticoagulation if needed as per clinical AF guidelines
☐	Liver function tests	☐	Concomitant medications
☐	Serum creatinine level		

Planned assessments for the 6 months following initiation of treatment

☐ Serial ECGs, at least every 6 months

☐ Liver function tests:

☐ Day 7

☐ Month 1 ☐ Month 2 ☐ Month 3

☐ Month 4 ☐ Month 5 ☐ Month 6

☐ Serum creatinine level at Day 7

Planned assessments from Month 6 to Year 1

☐ ECG at Month 12

☐ Liver function tests at Month 9

☐ Liver function tests at Month 12

Planned assessments beyond Year 1

☐ Serial ECGs, at least every 6 months

☐ Periodic liver function tests

Call for reporting:
Healthcare professionals should report any serious adverse events suspected to be associated with the use of Multaq to Sanofi-Aventis Malta Ltd., Triq Kan. K. Pirotta, B'Kara. BKR 1114. Tel: 21493022, fax 21493024

Alternatively any suspected adverse reactions can also be reported to
Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or at: http://www.medicinesauthority.gov.mt/pub/adr.doc