Patients treated with MULTAQ® (dronedarone)

Please counsel your patients regarding the following:

- to consult a physician if they develop **signs of AF recurrence** such as palpitations, sensation of rapid or irregular heart beats
- to consult a physician if they develop or experienceworsening **signs or symptoms of heart failure** such as weight gain, dependent oedema, or increased dyspnoea
- to immediately report **any symptoms of potential liver injury** such as sustained new-onset abdominal pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine or itching
- to consult a physician if they develop **signs of lung toxicity** such as breathlessness or non-productive cough
- if patients consult other doctors they should inform them about their **MULTAQ® treatment**

Be aware of the following warnings before prescribing and during treatment with MULTAQ®:

Careful monitoring and clinical evaluation is recommended:

- **Serial ECGs**, at least every 6 months. If patient develops permanent AF, treatment with MULTAQ® should be discontinued.
- **For symptoms of Congestive Heart Failure and for the development of left ventricular systolic dysfunction** during treatment. If heart failure or left ventricular systolic dysfunction develops, treatment with MULTAQ® should be discontinued.
- **Liver function tests** prior to initiation of treatment, after one week and after one month and then repeated monthly for six months, at months 9 and 12, and periodically thereafter. If ALT levels are confirmed to be ≥ 3 × ULN, treatment with MULTAQ® should be withdrawn.
- **Serum creatinine values** prior to and 7 days after initiation. If an increase in creatininemia is observed, serum creatinine should be re-measured after a further 7 days. If serum creatinine continues to rise then consideration should be given to further investigation and discontinuing treatment.
- **For pulmonary toxicity.** If confirmed, treatment should be discontinued.

[Please refer to the enclosed SmPC, section 4.4]

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

MULTAQ® Information Card (MIC)

[Version dated 12 August 2012]

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.

[Please refer to the enclosed SmPC, section 4.1]

Treatment with MULTAQ® should be initiated and monitored only under specialist supervision.

Treatment with MULTAQ® can be initiated in an outpatient setting.

[Please refer to the enclosed SmPC, section 4.2]

Please note:

This card does not include all warnings and contraindications.

Please refer to the enclosed SmPC before prescribing MULTAQ® (dronedarone) and during treatment.

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MULTAQ® contraindications and warnings

MULTAQ® is contraindicated and must not be used in:

- **Permanent AF with an AF duration ≥ 6 months (or duration unknown) and attempts to restore sinus rhythm no longer considered** by the physician
- **Patients in unstable hemodynamic conditions**
- **History of, or current heart failure or left ventricular systolic dysfunction**
- **Patients with liver and lung toxicity related to the previous use of amiodarone**
- **Severe hepatic impairment**
- **Severe renal impairment** (CrCl <30ml/min)

[Please refer to the enclosed SmPC, sections 4.3 and 4.4]

Special warnings and precautions for use

- **Careful monitoring during MULTAQ® administration is recommended by regular assessment of cardiac, hepatic and pulmonary function.**
- **If AF reoccurs discontinuation of MULTAQ® should be considered.**
- **Treatment with MULTAQ® should be stopped during the course of treatment, in case the patient develops any of the conditions which would lead to a contraindication.**
- **There is limited information on the optimal timing to switch from amiodarone to MULTAQ®. It should be considered that amiodarone may have a long duration of action after discontinuation due to its long half life.**

[Please refer to the enclosed SmPC, section 4.4]

Color codes: Contraindication / warning | Not recommended | Use with caution

MULTAQ® drug interactions

MULTAQ® is contraindicated and must not be used in combination with:

- **CYP3A4 inhibitors** including ketoconazole, itraconazole, voriconazole, posaconazole, telithromycin, clarithromycin, nefazodone and ritonavir
- **Potential torsades de pointes inducers** including phenothiazines, cisapride, bepridil, tricyclic antidepressants, terfenadine and certain oral macrolides (such as erythromycin)
- **Class I or Class III antiarrhythmics** such as flecainide, propafenone, quinidine, disopyramide, dofetilide, sotalol, amiodarone
- **Dabigatrin**

[Please refer to the enclosed SmPC, sections 4.2, 4.3 and 4.4]

MULTAQ® is not recommended with:

- **Grapefruit juice**
- **Potent CYP3A4** inducers including rifampicin, phenobarbital, carbamazepine, phenytoin, St. John's Wort

[Please refer to the enclosed SmPC, sections 4.4 and 4.5]

Use MULTAQ® with caution in association with:

- **Digoxin, beta blockers, calcium antagonists, statins:** dose adjustment should be considered and patients monitored.
- **Vitamin K antagonists such as warfarin:** INR should be closely monitored after initiating dronedarone as per their label and clinical AF guidelines.

[Please refer to the enclosed SmPC, sections 4.4 and 4.5]