INTRODUCING...

NEW

MULTAQ®

(dronedarone) Tablets 400mg

NDC 0024-4142-60

AVAILABLE IN

60 Count Bottles

Please see Important Safety Information on reverse side.

sanofi aventis

Because health matters

Please see accompanying full prescribing information, including boxed warning.

US.DRO.09.06.005

Indications and Usage

MULTAQ is an antiarrhythmic drug indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardiovascular risk factors (ie, age >70, hypertension, diabetes, prior cerebrovascular accident, left atrial diameter ≥50 mm or left ventricular ejection fraction [LVEF] <40%), who are in sinus rhythm or who will be cardioverted.

Contraindications

WARNING: HEART FAILURE

MULTAQ is contraindicated in patients with NYHA Class IV heart failure, or NYHA Class II-III heart failure with a recent decompensation requiring hospitalization or referral to a specialized heart failure clinic.

In a placebo-controlled study in patients with severe heart failure requiring recent hospitalization or referral to a specialized heart failure clinic for worsening symptoms (the ANDROMEDA Study), patients given dronedarone had a greater than two-fold increase in mortality. Such patients should not be given MULTAQ.

MULTAQ is also contraindicated in patients with second- or third-degree atrioventricular (AV) block or sick sinus syndrome (except when used in conjunction with a functioning pacemaker), bradycardia <50 bpm, QTc Bazett interval ≥500 msec, and severe hepatic impairment. MULTAQ should not be given to patients who are or may become pregnant (Category X) or nursing. MULTAQ should not be coadministered with strong CYP 3A inhibitors or drugs or herbal products that prolong the QT interval and might increase the risk of Torsade de Pointes.

New or Worsening Heart Failure

There are limited data available for AFib/AFL patients who develop worsening heart failure during treatment with MULTAQ. If heart failure develops or worsens, consider the suspension or discontinuation of MULTAQ.

Electrolyte Levels

Hypokalemia and hypomagnesemia may occur with concomitant administration of potassium-depleting diuretics. Potassium levels should be within the normal range prior to administration of MULTAQ and maintained in the normal range during administration of MULTAQ.

QT Interval Prolongation

MULTAQ induces a moderate (average of about 10 msec) QTc (Bazett) prolongation. If the QTc Bazett interval is ≥500 msec, MULTAQ should be stopped.

Increase in Creatinine

Serum creatinine levels increase by about 0.1 mg/dL following MULTAQ treatment initiation. The elevation has a rapid onset, reaches a plateau after 7 days and is reversible after discontinuation. If an increase in serum creatinine occurs and plateaus, this increased value should be used as the patient's new baseline. The change in creatinine levels has been shown to be the result of an inhibition of creatinine's tubular secretion, with no effect upon the glomerular filtration rate.

Drug-Drug Interactions

Treatment with Class I or III antiarrhythmics or drugs that are strong inhibitors of CYP 3A must be stopped before starting MULTAQ (see Contraindications). Patients should be instructed to avoid grapefruit juice beverages while taking MULTAQ. Calcium channel blockers and beta-blockers could potentiate the effects of MULTAQ on conduction.

Increased digoxin levels have been observed when MULTAQ was coadministered with digoxin. Digoxin can potentiate the electrophysiologic effects of MULTAQ (such as decreased AV-node conduction); the need for digoxin therapy should be reconsidered when prescribing MULTAQ. If digoxin treatment is continued, halve the dose of digoxin, monitor serum levels closely, and observe for toxicity.