

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

**Do not prescribe MULTAQ for patients with NYHA Class IV heart failure (HF) or NYHA Class II–III HF with recent decompensation requiring hospitalization or referral to a specialized HF clinic**

**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 dronedarone.**

**Prescribers should also be aware of other important contraindications, including:**

- Coadministration of strong CYP3A4 inhibitors, medicinal products inducing Torsade de Pointes, or Class I or III antiarrhythmic agents
- Second- or third-degree atrioventricular block, sick sinus syndrome (except when used in conjunction with a functioning pacemaker), or bradycardia of <50 bpm
- QTc Bazett  $\geq$ 500 ms or PR interval >280 ms
- Severe hepatic impairment
- Pregnancy or nursing mothers

## Please consider the following *Steps for Ensuring Appropriate Use* when prescribing MULTAQ for your patients:

### 1. Initiate MULTAQ in appropriate patients

- Screen patients for severity and stability of heart failure; MULTAQ should not be initiated in patients with NYHA Class IV heart failure or NYHA Class II–III heart failure with recent decompensation requiring hospitalization or referral to a specialized heart failure clinic
- Treatment may be initiated in an outpatient or an inpatient setting
- Discontinue use of other Class I or Class III antiarrhythmic therapies
- The dosage of certain cardiovascular medications may need to be adjusted and certain laboratory test changes may occur

### 2. Counsel patients to report changes in their symptoms and their medications

- Advise patients to consult a physician if they develop signs or symptoms of worsening heart failure such as weight gain, dependent edema, and/or increasing shortness of breath
- Advise patients that MULTAQ should not be taken with certain other medications and to consult with their physicians before starting any new drugs as the dosage of certain cardiovascular medications may need to be adjusted
- Refer patients to the Medication Guide and address any additional questions

### 3. Check patients for changes in their symptoms or certain lab tests

- Observe patients regularly for signs or symptoms of heart failure that may require additional treatment and/or MULTAQ discontinuation
- Be aware that within a week, MULTAQ causes a small change in serum creatinine that does not reflect a change in underlying renal function

***In patients with developing or worsening heart failure during treatment, use clinical judgment to guide the management of each patient based on individual benefit/risk assessment, and consider the suspension or discontinuation of MULTAQ therapy.***

Please refer to the enclosed Prescribing Information for complete safety information before prescribing MULTAQ.

### Serious Adverse Events:

Health care professionals should report any serious adverse events thought to be associated with MULTAQ use to:

- Sanofi-aventis at 1-800-633-1610 option 2
- FDA's MedWatch reporting system
  - By phone (1-800-FDA-1088)
  - By facsimile (1-800-FDA-0178)
  - Online (<https://www.accessdata.fda.gov/scripts/medwatch/>)
  - By mail (using the MedWatch Voluntary Reporting form 3500, to the FDA Safety Information and Adverse Event Reporting Program: Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787)

### Additional Resources

For additional information:

- Talk to your sanofi-aventis sales representative or call the sanofi-aventis Medical Information Services department at 1-800-633-1610 option 1
- Visit [www.MULTAQ.com](http://www.MULTAQ.com)
- Refer patients to the MULTAQ Medication Guide

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Because health matters

PLEASE SEE FULL PRESCRIBING INFORMATION INCLUDING BOXED WARNING