



## Preferred Drug List

### NEW DRUG REVIEW

**Proprietary Name:** Multaq®

**Common Name:** Dronedarone

**PDL Category:** Antiarrhythmics

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Amiodarone	Preferred

#### Summary

**Indications and Usage:** Anti-arrhythmic 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, who are in sinus rhythm or who will be cardioverted.<sup>1</sup>

**Mechanism of Action:** Exact mechanism of action is unknown.<sup>1</sup>

**Dosage Forms:** Tablets: 400mg

**Recommended Dosage:** 400mg twice daily with morning and evening meals.<sup>1</sup>

**Common Adverse Drug Reactions:** Diarrhea, nausea, vomiting, abdominal pain, asthenia, cutaneous rash.<sup>1</sup>

**Contraindications:** Class IV heart failure or symptomatic heart failure with a recent decompensation. Second or third degree atrioventricular (AV) block or sinus syndrome (except when used in conjunction with a functioning pacemaker). Bradycardia < 50bpm. Concomitant use with a strong CYP3A inhibitor. Concomitant use of drugs or herbal products that prolong the QT interval. QTc Bazett interval ≥ 500ms. Severe hepatic impairment. Pregnancy. Nursing Mothers.<sup>1</sup>

**Manufacturer:** Sanofi-Aventis U.S., LLC

**Analysis:** Multaq® is a new anti-arrhythmic indicated for the treatment of persistent atrial fibrillation. In the trials used to gain FDA approval, Multaq® was compared only to placebo. Multaq®, which is structurally similar to amiodarone, has less risk of serious toxicities and does not interact with warfarin. Multaq® doubles the risk of mortality in patients with severe heart failure. Multaq® has similar clinical efficacy (except in patients with severe heart failure), an improved side effect profile, and no drug interaction with warfarin as compared to preferred alternatives on the Preferred Drug List. Therefore, it is recommended that Multaq® be added to the Preferred Drug List as a preferred drug.

**IME Recommendation:**  Preferred Drug  Recommended Drug  
 Non-Preferred Drug  Non-Recommended Drug  
 Preferred Drug with Conditions

1. Multaq® [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; 2009.