

Dronedarone (Multaq®) Considerations for Use*

US/FDA Approved Indications: Reduce hospitalization risk for atrial fib in patients in sinus rhythm with history of paroxysmal or persistent atrial fib

Black Box Warning*	Increased risk of death, stroke, and heart failure in patients with decompensated heart failure or permanent atrial fib. Do not use with permanent atrial fib, symptomatic heart failure with recent decompensation requiring hospitalization, or NYHA Class IV heart failure.
Mechanism of Action	Has sodium channel blockade, beta adrenergic blockade, cardiac repolarization, and calcium channel blockade effects (Class I, II, III, IV effects).
Dosing[†]	<u>Maintenance</u>: 400 mg PO twice daily with meals <u>Hepatic Impairment</u>: Contraindicated in severe impairment <u>Renal Impairment</u>: No dosage adjustment needed
Contraindications	• <u>permanent atrial fib (normal sinus rhythm will not or cannot be restored)</u> • <u>recently decompensated heart failure requiring hospitalization or NYHA Class IV heart failure</u> • 2nd or 3rd degree AV block or sick sinus syndrome without functioning pacemaker • bradycardia < 50 bpm • QTc Bazett interval $\geq$ 500 ms • concomitant use of strong CYP 3A4 inhibitor • concomitant use of drugs or herbs that prolong QT interval and may induce Torsades de Pointes • liver or lung toxicity related to previous amiodarone use • severe hepatic impairment • pregnancy or nursing mothers
Major Side Effects	heart block, heart failure, bradycardia, stroke, death, hepatic toxicity, pulmonary toxicity
Dosage forms and Strengths	<u>PO</u> : 400 mg tablets
Special Notes	Monitor EKG every 3 months; if in atrial fib, then either stop dronedarone or cardiovert. Use appropriate antithrombotic therapy prior to and concurrently with dronedarone. If suspected hepatic injury or confirmed pulmonary toxicity occurs, discontinue use. Potassium and magnesium levels should be within normal range prior to initiating and during therapy. Monitor serum creatinine periodically. Has many drug interactions, including warfarin.
Counseling	Report symptoms of new or worsening heart failure (ex. wt gain, edema, SOB). Report symptoms of hepatic injury (ex. anorexia, nausea, vomiting, fatigue, malaise, right upper quadrant discomfort, jaundice, dark urine). Take with food. Avoid grapefruit juice Consult with a healthcare provider prior to new drug use (including OTC and herbals)

*Refer to prescribing information for more complete information.

†Dosages given in the table may differ from those recommended by the manufacturers.

Sources:

1. American College of Cardiology (ACC), American Heart Association (AHA), and the European Society of Cardiology (ESC). *ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation*. Washington, DC: American College of Cardiology.
2. Heart Rhythm Society. *AF360 Pocket Guide: Practical Rate and Rhythm Management of Atrial Fibrillation*. 2010, Washington, DC: Heart Rhythm Society.
3. *Multaq® Prescribing Information, 9/7/12*