# Dronedarone (Multaq®) Considerations for Use*

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

<table>
<thead>
<tr>
<th><strong>Black Box Warning</strong></th>
<th>Increased risk of death, stroke, and heart failure in patients with decompensated heart failure or permanent atrial fibr. Do not use with permanent atrial fibr, symptomatic heart failure with recent decompensation requiring hospitalization, or NYHA Class IV heart failure.</th>
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</thead>
<tbody>
<tr>
<td><strong>Mechanism of Action</strong></td>
<td>Has sodium channel blockade, beta adrenergic blockade, cardiac repolarization, and calcium channel blockade effects (Class I, II, III, IV effects).</td>
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</table>
| **Dosing** | **Maintenance**: 400 mg PO twice daily with meals  
**Hepatic Impairment**: Contraindicated in severe impairment  
**Renal Impairment**: No dosage adjustment needed |
| **Contraindications** | • permanent atrial fibr (normal sinus rhythm will not or cannot be restored)  
• recently decompensated heart failure requiring hospitalization or NYHA Class IV heart failure  
• 2nd or 3rd degree AV block or sick sinus syndrome without functioning pacemaker  
• bradycardia < 50 bpm  
• QTc Bazett interval > 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** | PO: 400 mg tablets |
| **Special Notes** | Monitor EKG every 3 months; if in atrial fibr, 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 herbs) |

*Refer to prescribing information for more complete information.*
†Dosages given in the table may differ from those recommended by the manufacturers.

Sources:
3. Multaq® Prescribing Information, 9/7/12