

## BC AFC Dronedarone Initiation and Titration Pathway (For Prescribers)

**Document Purpose:** Standardized recommendations for initiation of dronedarone and ongoing monitoring/patient management

### Clinical Indication:

- Symptomatic AF in the absence of significant heart failure or liver abnormalities

### Absolute Contraindications:

- Permanent AF
- Heart failure with recent decompensation requiring hospitalization
- Left ventricular systolic dysfunction (LVEF <40%)
- High degree atrioventricular conduction disorders (unless functioning pacemaker is present)
- Patients with previous lung or liver injury related to prior use of amiodarone
- Pre-existing QTc prolongation (congenital or acquired long QT syndromes)
  - Consider avoiding dronedarone in the presence of a QTc >440 msec (men) or >460 msec (women) in the absence of a pre-existing bundle branch block
- Severe hepatic impairment

### Relative Contraindications (caution for use):

- Sinus bradycardia (<50 bpm)
- Hypokalemia or hypomagnesemia (correct imbalances prior to use and throughout therapy)
- Concomitant use of strong CYP3A inhibitors (ketoconazole, itraconazole, voriconazole, cyclosporine, telithromycin, clarithromycin, nefazodone, and ritonavir)

### Baseline Investigations:

- Blood pressure
- ECG (within 1 week)
- Echocardiogram (or other assessment of LV function; within 1 year)
- Laboratory investigations (within 1 week) - Serum electrolytes, LFTs, and Serum Creatinine/eGFR

### Dosing:

- 400 mg BID

### Monitoring:

Parameter	Frequency	Considerations
ECG	<p>Within 7 days of initiation</p> <p>Every 6-12 months if stable</p>	<p>Notify prescriber if any of the following develop:</p> <ul style="list-style-type: none"> <li>• &gt;25% increase from baseline QTc (&gt;500ms)</li> <li>• Heart rate &lt;50 bpm</li> </ul> <p>If prescriber not immediately available then consider reducing dose or temporary discontinuation</p>

Patient response	With initiation and at each patient follow-up appointment	<ul style="list-style-type: none"> <li>• If symptoms improved and/or decreased frequency of episodes: <ul style="list-style-type: none"> <li>○ Maintain at current dose and arrange follow-up (including Holter) as per algorithm.</li> </ul> </li> <li>• If no/minimal improvement in AF symptoms <ul style="list-style-type: none"> <li>○ Notify prescriber to discuss alternative therapies</li> </ul> </li> <li>• If AF persists and sinus rhythm cannot be restored <ul style="list-style-type: none"> <li>○ Discontinue dronedarone</li> </ul> </li> </ul>
Medication Tolerance	With initiation and at each patient follow-up appointment	<ul style="list-style-type: none"> <li>• Syncope <ul style="list-style-type: none"> <li>○ Discontinue dronedarone, report to ER</li> </ul> </li> <li>• Exacerbation/New onset of HF symptoms <ul style="list-style-type: none"> <li>○ Strongly consider holding dronedarone pending the outcome of clinical review</li> </ul> </li> <li>• Dizziness/lightheadedness <ul style="list-style-type: none"> <li>○ Notify MD/NP if acute onset, severe, or persistently problematic for the patient</li> </ul> </li> <li>• Nausea, diarrhea <ul style="list-style-type: none"> <li>○ Supportive measures (up to 1 month)</li> <li>○ Notify prescriber if symptoms persists and are problematic</li> </ul> </li> <li>• Symptoms of liver injury (as outlined below) <ul style="list-style-type: none"> <li>○ Obtain LFTs and notify prescriber</li> </ul> </li> </ul>
24 hour Holter Monitor	Once patient stable	<ul style="list-style-type: none"> <li>• Arrange for Holter and follow-up visit (in-clinic or telehealth) in 3-6 months (or as previously scheduled)</li> </ul>
Labs (Liver Panel and bilirubin)	Every 3 months for the first year then every 6 months	

**Patient counseling to include:**

- Report immediately any symptoms suggestive of:
  - Pulmonary toxicity (Dyspnea or non-productive cough)
  - Hepatic injury (anorexia, nausea, vomiting, fever, malaise, fatigue, RUQ pain, jaundice, dark urine, itching)

**Tapering / Discontinuation Schedule**

- Not applicable

**Wash-out period prior to initiating alternate antiarrhythmic**

- 3 days