

Suggested Prescriber Checklist for MULTAQ®



This suggested checklist can assist you when prescribing MULTAQ®. Treatment with MULTAQ® can be initiated in an outpatient setting. See the Product Monograph (PM) for full prescribing information, warnings and precautions, and adverse events.

MULTAQ® is indicated for the treatment of patients with paroxysmal or persistent atrial fibrillation (AF) who are in sinus rhythm or who are intended to be cardioverted, to reduce the risk of cardiovascular hospitalization due to AF. MULTAQ® should only be prescribed after alternative treatment options have been considered.

There is limited information on the optimal timing to switch from amiodarone to MULTAQ®. Amiodarone may have a long duration of action after discontinuation due to its long half life. If a switch is considered, this should be done under the supervision of a specialist.

If any of the criteria below is checked **YES**, **DO NOT** PRESCRIBE MULTAQ®.

| Medical Conditions | YES | NO |
|---|--------------------------|--------------------------|
| The patient has permanent AF of any duration in which sinus rhythm cannot be restored and attempts to restore it are no longer considered by the attending physician. | <input type="checkbox"/> | <input type="checkbox"/> |
| The patient has a history of, or current heart failure, regardless of NYHA functional class. | <input type="checkbox"/> | <input type="checkbox"/> |
| The patient has left ventricular systolic dysfunction (LVSD). | <input type="checkbox"/> | <input type="checkbox"/> |
| The patient has 2 nd or 3 rd degree atrio-ventricular (AV) block, complete bundle branch block, distal block, sinus node dysfunction, atrial conduction defects, or sick sinus syndrome (except when used in conjunction with a functioning pacemaker). | <input type="checkbox"/> | <input type="checkbox"/> |
| Patients in unstable hemodynamic condition(s). | <input type="checkbox"/> | <input type="checkbox"/> |
| The patient has bradycardia (<50 beats per minute). | <input type="checkbox"/> | <input type="checkbox"/> |
| The patient has liver or lung toxicity related to the previous use of amiodarone. | <input type="checkbox"/> | <input type="checkbox"/> |
| The patient has a QTc Bazett interval ≥500 milliseconds. | <input type="checkbox"/> | <input type="checkbox"/> |
| The patient has severe hepatic impairment. | <input type="checkbox"/> | <input type="checkbox"/> |
| The patient is pregnant or breastfeeding. | <input type="checkbox"/> | <input type="checkbox"/> |
| The patient has hypersensitivity to dronedarone or to any of the excipients or component of the container. | <input type="checkbox"/> | <input type="checkbox"/> |

* See the MULTAQ® Product Monograph for complete details at www.sanofi.ca or by contacting the sponsor at 1-800-265-7927.

| Concomitant Medications | YES | NO |
|---|--------------------------|--------------------------|
| The patient is currently being treated with strong (CYP) 3A4 inhibitors (e.g. ketoconazole, itraconazole, voriconazole, cyclosporin, clarithromycin, and ritonavir). | <input type="checkbox"/> | <input type="checkbox"/> |
| The patient is using medicinal products inducing torsades de pointes (e.g. phenothiazines, tricyclic antidepressants and certain oral macrolides, Class I and III antiarrhythmics). | <input type="checkbox"/> | <input type="checkbox"/> |

The following monitoring assessments are recommended before starting and during MULTAQ® therapy.*

| Recommended assessments at initiation of MULTAQ | | | |
|---|--|--------------------------|--|
| <input type="checkbox"/> | Cardiovascular status | <input type="checkbox"/> | Anticoagulation if needed |
| <input type="checkbox"/> | Concomitant medications | <input type="checkbox"/> | Digoxin, beta-blockers, calcium antagonists, statins, tacrolimus, sirolimus, potent CYP3A4 inducers (<i>due to drug interaction</i>) |
| <input type="checkbox"/> | Concomitant use of dabigatran is not recommended | | |

| Recommended assessments following initiation of treatment | |
|---|--|
| <input type="checkbox"/> | ECG is recommended at least every 6 months. |
| <input type="checkbox"/> | If patient develops heart failure, LVSD or permanent AF, MULTAQ® should be discontinued. |
| <input type="checkbox"/> | Periodic hepatic serum enzymes testing (<i>especially during the first 6 months of treatment</i>). |
| <input type="checkbox"/> | Baseline value of plasma creatinine should be established 7 days after initiation of treatment with MULTAQ®. |
| <input type="checkbox"/> | INR should be closely monitored in patients taking vitamin K antagonists as per their label. |
| <input type="checkbox"/> | Renal function should be monitored periodically. |
| <input type="checkbox"/> | Pulmonary clinical evaluation: MULTAQ® should be discontinued if pulmonary toxicity is confirmed. |



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