

For patients with paroxysmal or persistent AFib

## MULTAQ (dronedarone) offers reimbursement support

### Have questions about patient access to MULTAQ?

#### Frequently asked questions about reimbursement support for MULTAQ

##### Whom can I contact with questions about MULTAQ coverage?

Call [Sanofi Patient Connection™](#)

**1-888-847-4877**

Monday through Friday 9:00 AM – 8:00 PM Eastern Time

##### What if my patient can't afford MULTAQ because of the co-pay amount?

Several resources may help your patient handle cost issues:

- With the MULTAQ Savings Card, your eligible patients may have a \$0 co-pay and can get up to a maximum commercial benefit of \$3,000 (maximum savings of up to \$700 per monthly fill) or get up to \$150 off per fill for cash payments through 12/31/19.\*† Eligible patients can get a Savings Card by registering at <https://www.multaq.com/multaq-savings> or by calling 866-255-8830
- If your patient has a limited income, remind him/her to call the [Sanofi Patient Connection™](#). Reimbursement Counselors may investigate a patient's eligibility for programs such as the Sanofi U.S. Patient Assistance Program, or they may have information about alternative patient assistance services through local, state, or national programs
- Use a [Medicare Part D Profile Form](#) to determine if your patient is enrolled in the federal low-income subsidy program, which would lower his/her MULTAQ co-pay

\*Eligible commercially insured patients may receive a savings of up to \$700 per monthly fill, up to 13 fills. Maximum annual benefit of \$3,000. Eligible cash patients may receive a savings of up to \$150 per monthly fill, up to 13 fills. Maximum annual benefit of \$1,950. Sanofi US reserves the right to rescind, revoke, or amend this offer without notice. Certain restrictions apply. See details on savings card. Expires: 12/31/19.

†This offer is not valid for prescriptions covered by or submitted for reimbursement under Medicaid, Medicare, VA, DOD, TRICARE, or similar federal or state programs including any state pharmaceutical assistance program. Important to note that if you have an Affordable Care (Health Care Exchange) plan, you may still be qualified to receive and use this savings card. Also, if you have a Federal Employee Health Benefits (FEHB) plan with commercial/private insurance, you may be qualified to receive and use this savings card. This program is not valid where prohibited by law.

#### Indication

MULTAQ is an antiarrhythmic drug indicated to reduce the risk of hospitalization for atrial fibrillation (AFib) in patients in sinus rhythm with a history of paroxysmal or persistent AFib.

#### Important Safety Information for MULTAQ® (dronedarone)—Boxed WARNING

**WARNING: INCREASED RISK OF DEATH, STROKE AND HEART FAILURE IN PATIENTS WITH DECOMPENSATED HEART FAILURE OR PERMANENT ATRIAL FIBRILLATION**

**MULTAQ is contraindicated in patients with symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure. MULTAQ doubles the risk of death in these patients.**

**MULTAQ is contraindicated in patients in atrial fibrillation (AFib) who will not or cannot be cardioverted into normal sinus rhythm. In patients with permanent AFib, MULTAQ doubles the risk of death, stroke, and hospitalization for heart failure.**

**Please see additional Important Safety Information on page 3.**

**Please [click here for full Prescribing Information, including boxed WARNING](#), or visit [MULTAQ.com/hcp](https://www.multaq.com/hcp).**

## Frequently asked questions about reimbursement support for MULTAQ® (dronedarone)

### If my patient is not eligible for the MULTAQ Savings Card and cannot afford his/her MULTAQ prescription, where can he/she find assistance?

- Your patient may be eligible for the Sanofi U.S. Patient Assistance Program, which provides medication free of charge for eligible patients
- You or your patient can call the [Sanofi Patient Connection™](#) at 1-888-847-4877 to find out whether he/she qualifies for patient assistance

### What if my patient does not have prescription drug coverage?

Sanofi U.S. has resources that may help your patient who has no insurance coverage.

- For patients with no prescription drug insurance, visit the [Patient Rx Savings](#) section of this website to learn about the MULTAQ Savings Card
- You or your patient can call the [Sanofi Patient Connection™](#) at 1-888-847-4877 to find out whether he/she qualifies for patient assistance

### What if my patient's health plan does not cover MULTAQ?

- For patients whose health plan does not cover MULTAQ, you can request a medical exception for your patient who is appropriate for MULTAQ therapy. Reimbursement Counselors at the [Sanofi Patient Connection™](#) can help you locate the appropriate forms

For patients in Medicare Part D plans, a [Medicare Part D Coverage Determination Request Form](#) must be completed to request a medical exception

### I'm not sure how to request an appeal or obtain a prior authorization (PA) for one of my patients. What should I do?

- You or your patient should call the [Sanofi Patient Connection™](#) at 1-888-847-4877. Reimbursement Counselors may be able to help your eligible patients with appeals, prior authorizations, and other cost and coverage questions
- Or fill out the [enrollment form](#) and FAX at 1-888-847-1797 or mail to the [Sanofi Patient Connection™](#). The form can also be obtained by accessing the Provider Portal link on the [Sanofi Patient Connection™](#) website, then look for Quick Links. Detailed instructions are provided on the form

### Prior authorization has been approved, but my patient still cannot afford the co-pay. What can I do?

You or your patient should call the [Sanofi Patient Connection™](#) at 1-888-847-4877. Reimbursement Counselors may be able to help your eligible patients with co-pay assistance, or they may refer interested patients to alternative patient assistance services through local, state, or national programs.

Please [click here for full Prescribing Information, including boxed WARNING](#), or visit [MULTAQ.com/hcp](#).

# IMPORTANT SAFETY INFORMATION FOR MULTAQ® (dronedarone)

**WARNING:  
INCREASED RISK OF DEATH, STROKE AND  
HEART FAILURE IN PATIENTS WITH DECOMPENSATED HEART  
FAILURE OR PERMANENT ATRIAL FIBRILLATION**

**MULTAQ is contraindicated in patients with symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure. MULTAQ doubles the risk of death in these patients.**

**MULTAQ is contraindicated in patients in atrial fibrillation (AFib) who will not or cannot be cardioverted into normal sinus rhythm. In patients with permanent AFib, MULTAQ doubles the risk of death, stroke, and hospitalization for heart failure.**

**MULTAQ is also contraindicated in patients:**

- With second- or third-degree atrioventricular (AV) block or sick sinus syndrome (except when used in conjunction with a functioning pacemaker), bradycardia <50 bpm, QTc Bazett interval  $\geq$ 500 ms or PR interval  $>$ 280 ms
- Who are or may become pregnant (Category X) or nursing. MULTAQ may cause fetal harm when administered to a pregnant woman
- With concomitant use of strong CYP 3A inhibitors, such as ketoconazole, itraconazole, voriconazole, cyclosporine, telithromycin, clarithromycin, nefazodone, ritonavir, or drugs or herbal products that prolong the QT interval and might increase the risk of Torsade de Pointes, such as phenothiazine antipsychotics, tricyclic antidepressants, certain oral macrolide antibiotics, and Class I and III antiarrhythmics
- With liver or lung toxicity related to the previous use of amiodarone
- With severe hepatic impairment
- With hypersensitivity to the active substance or to any of the excipients

**Cardiovascular Death in NYHA Class IV or Decompensated Heart Failure**

MULTAQ is contraindicated in patients with NYHA Class IV heart failure or symptomatic heart failure with recent decompensation requiring hospitalization because it doubles the risk of death.

**Cardiovascular Death and Heart Failure in Permanent AFib**

MULTAQ doubles the risk of cardiovascular death (largely arrhythmic) and heart failure events in patients with permanent AFib. Patients treated with MULTAQ should undergo monitoring of cardiac rhythm no less often than every 3 months. Cardiovert patients who are in AFib (if clinically indicated) or discontinue MULTAQ. MULTAQ offers no benefit in subjects in permanent AFib.

**Increased Risk of Stroke in Permanent AFib**

In a placebo-controlled study in patients with permanent AFib, dronedarone was associated with an increased risk of stroke, particularly in the first two weeks of therapy. MULTAQ should only be initiated in patients in sinus rhythm who are receiving appropriate antithrombotic therapy.

**New Onset or Worsening Heart Failure**

New onset or worsening of heart failure has been reported during treatment with MULTAQ in the postmarketing setting. In a placebo-controlled study in patients with permanent AFib, increased rates of heart failure were observed in patients with normal left ventricular function and no history of symptomatic heart failure, as well as those with a history of heart failure or left ventricular dysfunction.

Advise patients to consult a physician if they develop signs or symptoms of heart failure, such as weight gain, dependent edema, or increasing shortness of breath. If heart failure develops or worsens and requires hospitalization, discontinue MULTAQ.

**Liver Injury**

Hepatocellular liver injury, including acute liver failure requiring transplant, has been reported in patients treated with MULTAQ in the postmarketing setting. Advise patients treated with MULTAQ to report immediately symptoms suggesting hepatic injury (such as anorexia, nausea, vomiting, fever, malaise, fatigue, right upper quadrant pain, jaundice, dark urine, or itching). Consider obtaining periodic hepatic serum enzymes, especially during the first 6 months of treatment. It is not known whether routine periodic monitoring of serum enzymes will prevent the development of severe liver injury. If hepatic injury is suspected, promptly discontinue MULTAQ and test

serum enzymes, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase, as well as serum bilirubin, to establish whether there is liver injury. If liver injury is found, institute appropriate treatment and investigate the probable cause. Do not restart MULTAQ in patients without another explanation for the observed liver injury.

**Pulmonary Toxicity**

Cases of interstitial lung disease including pneumonitis and pulmonary fibrosis have been reported in patients treated with MULTAQ in the post-marketing setting. Onset of dyspnea or non-productive cough may be related to pulmonary toxicity and patients should be carefully evaluated clinically. If pulmonary toxicity is confirmed, MULTAQ should be discontinued.

**Hypokalemia and Hypomagnesemia with Potassium-Depleting Diuretics**

Hypokalemia and hypomagnesemia may occur with concomitant administration of potassium-depleting diuretics. Potassium levels should be within the normal range prior to administration of MULTAQ and maintained in the normal range during administration of MULTAQ.

**QT Interval Prolongation**

MULTAQ induces a moderate (average of about 10 ms but much greater effects have been observed) QTc (Bazett) prolongation. If the QTc Bazett interval is  $\geq$ 500 ms, discontinue MULTAQ.

**Renal Impairment and Failure**

Marked increase in serum creatinine, pre-renal azotemia and acute renal failure, often in the setting of heart failure or hypovolemia, have been reported in patients taking MULTAQ. In most cases, these effects appear to be reversible upon drug discontinuation and with appropriate medical treatment. Monitor renal function periodically.

Small increases in creatinine levels (about 0.1 mg/dL) following MULTAQ treatment initiation have been shown to be a result of inhibition of creatinine's tubular secretion. The elevation has a rapid onset, reaches a plateau after 7 days and is reversible after discontinuation.

**Women of Childbearing Potential**

Premenopausal women who have not undergone a hysterectomy or oophorectomy must use effective contraception while using MULTAQ. Dronedarone caused fetal harm in animal studies at doses equivalent to recommended human doses. Counsel women of childbearing potential regarding appropriate contraceptive choices.

**Drug-Drug Interactions**

- Treatment with Class I or III antiarrhythmics or drugs that are strong inhibitors of CYP 3A must be stopped before starting MULTAQ (see Contraindications)
- Patients should be instructed to avoid grapefruit juice beverages while taking MULTAQ
- Calcium channel blockers with depressant effects and beta-blockers could increase the bradycardia effects of MULTAQ on conduction
- In the ANDROMEDA (patients with recently decompensated heart failure) and PALLAS (patients with permanent AFib) trials, baseline use of digoxin was associated with an increased risk of arrhythmic or sudden death in MULTAQ-treated patients compared to placebo. In patients not taking digoxin, no difference in risk of sudden death was observed in the MULTAQ vs placebo groups  
Digoxin can potentiate the electrophysiologic effects of MULTAQ (such as decreased AV-node conduction). MULTAQ increases exposure to digoxin  
Consider discontinuing digoxin. If digoxin treatment is continued, halve the dose of digoxin, monitor serum levels closely, and observe for toxicity
- Postmarketing cases of increased INR with or without bleeding events have been reported in warfarin-treated patients initiated with MULTAQ. Monitor INR after initiating MULTAQ in patients taking warfarin
- Statins: Avoid simvastatin doses greater than 10 mg daily. Follow statin label recommendations for use with CYP 3A and P-gP inhibitors such as MULTAQ

**Adverse Reactions**

In studies, the most common adverse reactions observed with MULTAQ were diarrhea, nausea, abdominal pain, vomiting, and asthenia.

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