

MULTAQ should be administered with a meal. Warn patients not to take MULTAQ with grapefruit juice.

If a dose is missed, patients should take the next dose at the regularly scheduled time and should not double the dose.

Advise patients to consult a physician if they develop signs or symptoms of worsening heart failure such as acute weight gain, dependent edema, or increasing shortness of breath.

Advise patients to immediately report any symptoms of potential liver injury (such as anorexia, nausea, vomiting, fever, malaise, fatigue, right upper quadrant abdominal discomfort, jaundice, dark urine or itching) to their physician.

Advise patients to inform their physician of any history of heart failure, rhythm disturbance other than atrial fibrillation or flutter or predisposing conditions such as uncorrected hypokalemia.

MULTAQ may interact with some drugs; therefore, advise patients to report to their doctor the use of any other prescription, non-prescription medication or herbal products, particularly St. John's wort.

## 17.2 Medication Guide

### Medication Guide

#### MULTAQ (MUL-tak)

#### (dronedarone)

#### Tablets

Read this Medication Guide before you start taking MULTAQ and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

### What is the most important information I should know about MULTAQ?

- 1. MULTAQ is not for people with severe heart failure. People with severe heart failure who take MULTAQ have an increased chance of dying.** Heart failure means your heart does not pump blood through your body as well as it should.

#### Do not take MULTAQ if you have severe heart failure:

- **where any physical activity causes shortness of breath or you have shortness of breath while at rest or after a small amount of exercise.**
- **if you were hospitalized for heart failure within the last month even if you are better now.**

Call your doctor right away if you have any signs and symptoms of worsening heart failure:

- shortness of breath or wheezing at rest
- wheezing, chest tightness or coughing up frothy sputum at rest, nighttime or after minor exercise

- trouble sleeping or waking up at night because of breathing problems
- using more pillows to prop yourself up at night so you can breathe more easily
- gaining more than 5 pounds quickly
- increasing swelling of feet or legs

**2. MULTAQ may cause liver problems, including life-threatening liver failure.** Your doctor may order blood tests to check your liver before you start taking MULTAQ and during treatment. In some cases MULTAQ treatment may need to be stopped.

Tell your doctor right away if you develop any of these signs and symptoms of liver problems:

- loss of appetite, nausea, vomiting
- fever, feeling unwell, unusual tiredness
- itching
- yellowing of the skin or the whites of the eyes (jaundice)
- unusual darkening of the urine
- right upper stomach area pain or discomfort

### **What is MULTAQ?**

MULTAQ is a prescription medicine used to lower the chance that you would need to go into the hospital for heart problems. It is meant for people who have had an abnormal heart rhythm called atrial fibrillation or atrial flutter in the last six months but who do not have that abnormal rhythm now or are about to be converted to a normal rhythm. It may be safely used for people who have had atrial fibrillation and atrial flutter who also have medical problems such as high blood pressure, stroke or diabetes.

It is not known if MULTAQ is safe and effective in children younger than age 18 years old.

### **Who should not take MULTAQ?**

See “What is the most important information I should know about taking MULTAQ?”

**Do not take MULTAQ if:**

- **You have severe heart failure or have recently been in the hospital for heart failure, even if you are better now.**
- **You have severe liver problems.**
- **You take certain medicines that can change the amount of MULTAQ that gets into your body. Do not use these medicines with MULTAQ:**
  - Nefazodone for depression
  - Norvir<sup>®</sup> (ritonavir) for HIV infection
  - Nizoral<sup>®</sup> (ketoconazole), and Sporanox<sup>®</sup> (itraconazole), and Vfend<sup>®</sup> (voriconazole) for fungal infections
  - Ketek<sup>®</sup> (telithromycin), Biaxin<sup>®</sup> (clarithromycin) for bacterial infections
  - Cyclosporine for organ transplant
- **You take certain medicines that can lead to a dangerous abnormal heart rhythm:**
  - Some medicines for mental illness called phenothiazines
  - Some medicines for depression called tricyclic antidepressants
  - Some medicines for abnormal heart rhythm or fast heartbeat
  - Some medicines for bacterial infection

Ask your doctor if you are not sure if your medicine is one that is listed above.

- **You are pregnant or plan to become pregnant.** It is not known if MULTAQ will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
  - Women who may become pregnant should use effective birth control (contraception) while taking MULTAQ. Talk to your doctor about the best birth control methods for you.
- **You are breast-feeding or plan to breastfeed.** It is not known if MULTAQ passes into your breast milk. You and your doctor should decide if you will take MULTAQ or breastfeed. You should not do both.

### **What should I tell my doctor before starting MULTAQ?**

- If you have any other heart problems
- Tell your doctor about all the medicines you take, including any new medicines. Include all prescription and non-prescription medicines, vitamins and herbal remedies. MULTAQ and certain other medicines can react with each other, causing serious side effects. **Know the medicines you take.** Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

### **Be sure to tell your doctor and pharmacist if you take:**

- medicine for high blood pressure, chest pain, or other heart conditions
- statin medicine to lower blood cholesterol
- medicine for TB (tuberculosis)
- medicine for seizures
- medicine for organ transplant
- herbal supplement called St. John's wort

Some of these medicines could keep MULTAQ from working well or make it more likely for you to have side effects.

### **How should I take MULTAQ?**

- Take MULTAQ exactly as your doctor tells you.
- Take MULTAQ two times a day with food, once with your morning meal and once with your evening meal.
- Do not stop taking MULTAQ even if you are feeling well for a long time. The medicine may be working.
- If you miss a dose, wait and take your next dose at your regular time. Do not take 2 doses at the same time. Do not try to make up for a missed dose.

### **What should I avoid while taking MULTAQ?**

Do not drink grapefruit juice while you take MULTAQ. Grapefruit juice can increase the amount of MULTAQ in your blood and increase the likelihood that you will have a side effect of MULTAQ.

### **What are the possible side effects of MULTAQ?**

MULTAQ may cause serious side effects, including:

- See **“What is the most important information I should know about MULTAQ?”**
- Slowed heartbeat (bradycardia)

The most common side effects of MULTAQ include:

- Stomach problems such as
  - diarrhea
  - nausea
  - vomiting
  - stomach area (abdominal) pain
  - indigestion
- feeling tired and weak
- skin problems such as redness, rash, and itching

Tell your doctor about any side effect that bothers you or that does not go away. These are not all the possible side effects of MULTAQ. For more information ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### **How should I store MULTAQ?**

Store MULTAQ at room temperature (59-86°F, or 15-30°C).

**Keep MULTAQ and all medicines out of the reach of children.**

### **General information about MULTAQ**

Medicines are sometimes used for purposes not mentioned in a Medication Guide. Do not use MULTAQ for a condition for which it was not prescribed. Do not give MULTAQ to other people, even if they have the same symptoms or condition. It may harm them.

This Medication Guide summarizes the most important information about MULTAQ. If you would like more information:

- Talk with your doctor
- Ask your doctor or pharmacist for information about MULTAQ that was written for health-care professionals
- For the latest information and Medication Guide, visit [www.sanofi-aventis.us](http://www.sanofi-aventis.us) or call sanofi-aventis Medical Information Services at 1-800-633-1610 option 1. The Medication Guide may have changed since this copy was printed.

### **What are the ingredients in MULTAQ?**

**Active ingredient:** dronedarone

**Inactive ingredients:** hypromellose, starch, crospovidone, poloxamer 407, lactose monohydrate, colloidal silicon dioxide, magnesium stearate polyethylene glycol 6000, titanium dioxide, carnauba wax

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Rx only

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1, rue de la Vierge

33440 Ambares, France

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sanofi-aventis U.S. LLC  
Bridgewater, NJ 08807