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?

MULTAQ can cause serious side effects.

Do not take MULTAQ if you:

1. **have symptoms of heart failure that recently worsened and you were hospitalized, or if you have severe heart failure.**

   MULTAQ doubles your risk of dying if you have these conditions. Heart failure means your heart does not pump blood through your body as well as it should.

Call your doctor right away if you have any signs or symptoms of heart failure during treatment with MULTAQ:

- 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. **have a type of atrial fibrillation (irregular heart rhythm) called permanent atrial fibrillation (AF).**
   You and your doctor may decide not to try to change your heart rhythm back to a normal heart rhythm or your heart rhythm cannot be changed back to a normal rhythm. If you have permanent AF and take MULTAQ, you have a higher risk of death, stroke, and needing to be treated in a hospital for your heart failure.

Your doctor will monitor your heart rhythm regularly to make sure your heartbeat keeps a normal rhythm.

Call your doctor right away if you notice that your pulse is irregular during treatment with MULTAQ. This is a sign that you are in atrial fibrillation.

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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.

Call your doctor right away if you develop any of these signs and symptoms of liver problems during treatment with MULTAQ:

- 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 will need to go into the hospital for atrial fibrillation. It is meant for people who have had certain types of atrial fibrillation (paroxysmal or persistent AF) in the past, but are now in normal rhythm.

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 a certain type of heart problem called heart block, and you do not have an implanted pacemaker**
- **you have a slow heart rate, less than 50 beats each minute**
- **you have severe liver problems or had liver or lung problems after using amiodarone (a medicine for abnormal heart rhythm)**
- **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® (ritonavir) for HIV infection
  - Nizoral® (ketoconazole), and Sporanox® (itraconazole), and Vfend® (voriconazole) for fungal infections
  - Ketek® (telithromycin), Biaxin® (clarithromycin) for bacterial infections
  - Cyclosporine for organ transplant

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- **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.

- **You are allergic to dronedarone or any of the other ingredients in MULTAQ**. See the end of this Medication Guide for a complete list of ingredients in MULTAQ.

What should I tell my doctor before taking MULTAQ?

Before taking MULTAQ, tell your doctor if you:

- have any other heart problems
- Have any other medical conditions

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. MULTAQ and certain other medicines can react with each other, causing serious side effects.

Especially 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
- digoxin (Lanoxin)
- warfarin (Coumadin, Jantoven), a blood thinner medicine
- medicine for organ transplant
- herbal supplement called St. John's wort

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

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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 without first talking to your doctor, even if you are feeling well for a long time.
- 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.
- If you take too much MULTAQ, call your doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking MULTAQ?
Do not drink grapefruit juice while you are being treated with 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)**

- **Inflammation of the lungs, including scarring and thickening**. Call your doctor if you develop shortness of breath or a dry cough during treatment with MULTAQ.
- **Low potassium and magnesium levels in your blood.** This can happen if you take certain water pills (diuretics) during treatment with MULTAQ. Your doctor may check you for this problem before and during treatment.
- **Changes in kidney function blood tests after starting MULTAQ**. Your doctor may check you for this during treatment.

The most common side effects of MULTAQ include:

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

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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 other than those listed 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 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.

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