

PART III: CONSUMER INFORMATION
MULTAQ®
Dronedarone hydrochloride

This leaflet is part III of a three-part "Product Monograph" published when MULTAQ® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MULTAQ. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

MULTAQ helps control abnormal heart rhythm called atrial (AF) fibrillation and can lower the risk for having to go into the hospital for heart problems.

MULTAQ has not been studied in children.

What it does:

MULTAQ is a prescription medicine used in adults to help control abnormal heart rate and rhythm called atrial fibrillation.

When it should not be used:

Do not take MULTAQ if:

- You have an allergy to dronedarone, the active ingredient in MULTAQ, or anything else in MULTAQ. See "What the nonmedicinal ingredients are" for a complete list of ingredients.
- You have heart problems such as heart block or very slow heart rate (bradycardia), unless you have a pacemaker.
- Your ECG (electrocardiogram), a record of the electrical activity of your heart shows a heart disorder called "prolonged QT corrected interval" (more than 500 msec).
- You have a severe heart problem with severe shortness of breath, swelling of your feet or legs, trouble breathing while lying down or sleeping, shortness of breath while moving around (signs of heart failure).
- You take certain medicines that can interact with MULTAQ. See the list under the heading "Do not use these medicines with MULTAQ".
- You have a type of atrial fibrillation called permanent atrial fibrillation. In permanent AF, a decision has been made not to change back your heart rhythm to normal.
- The percentage of blood leaving your heart each time it contracts is too low (condition called left ventricular dysfunction).
- You have severe liver or lung problems.
- You are pregnant. MULTAQ can harm your baby.
- You are breast-feeding. MULTAQ may pass into your milk. Do not take MULTAQ if you are breast-feeding. Do not breast-feed if you take MULTAQ.

Do not use these medicines with MULTAQ and inform your doctor and pharmacist if you are taking these medications:

- NORVIR® (ritonavir) for HIV infection
- NIZORAL® (ketoconazole) and SPORANOX® (itraconazole) for fungal infections
- BIAXIN® (clarithromycin) for infections
- Cyclosporine for organ transplant
- Some medicines that can affect how your heart beats:
 - Medicines for mental illness called phenothiazines such as chlorpromazine and thioridazine
 - Medicines for depression such as nortriptyline, ANAFRANIL® (chlomipramine)
 - Medicines for abnormal heart rhythm or fast heartbeat such as sotalol, CORDARONE® (amiodarone), dofetilide, TAMBOCOR® (flecainide), RYTHMOL® (propafenone)
- PRADAXA® (dabigatran) to thin your blood
- XARELTO® (rivaroxaban) to thin your blood

What the medicinal ingredient is:

dronedarone hydrochloride

What the nonmedicinal ingredients are:

carnauba wax, colloidal anhydrous silica, crospovidone, hypromellose, lactose monohydrate, macrogol 6000, magnesium stearate, maize starch, poloxamer 407 and titanium dioxide

What dosage forms it comes in:

Film coated tablets containing 400 mg dronedarone, as dronedarone hydrochloride.

WARNINGS AND PRECAUTIONS

BEFORE you use MULTAQ talk to your doctor or pharmacist if you are using:

- Medicine for high blood pressure, chest pain, or other heart conditions, such as:
 - verapamil, diltiazem, nifedipine, metoprolol, propranolol, atenolol, digoxin
 - benazepril and captopril in a therapeutic class called ACE inhibitors
 - losartan, and valsartan in a therapeutic class called ARBs
- Any of these medicines:
 - Fexofenadine, a medicine for allergy or hay fever
 - A medicine to treat cancer (doxorubicin)
 - Statin medicine to lower blood cholesterol such as atorvastatin (LIPITOR®) or simvastatin
 - Rifampicin used for tuberculosis
 - Erythromycin
 - Phenobarbital, carbamazepine, and phenytoin used for seizure disorders
 - St. John's Wort herbal medicine for depression

- Sirolimus and tacrolimus used for organ transplants
- Anticoagulant medications such as: warfarin (COUMADIN®), other vitamin K antagonists, dabigatran etexilate (PRADAXA®), rivaroxaban, edoxaban, and apixaban

Tell your doctor about all your heart problems, including if you have a problem when your heart does not pump the blood through your body as well as it should (heart failure). You should call your doctor right away if any of the following signs appear or if you already had them and they worsen:

- shortness of breath when moving around
- trouble breathing while lying down or sleeping
- swelling of your feet or legs
- weight increase

Tell your doctor about all your liver problems including life threatening liver failure. Your doctor will order blood tests to check your liver function before you start taking MULTAQ and during treatment. In some cases MULTAQ treatment may need to be stopped. You should call your doctor right away if any of the following signs and symptoms of liver problems appear:

- 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.

Tell your doctor about all your other health problems. Including:

- Any health problem that could lead to a low level of potassium or magnesium in your blood.

Tell your doctor if:

- You are pregnant, or planning to become pregnant.
- You are breast-feeding a baby.

Blood test and ECG while taking MULTAQ

While you are taking MULTAQ, your doctor may perform heart examination tests such as an ECG or/and may take blood tests to assess your medical condition and how you tolerate the treatment. The results of one of the blood tests for kidney function (blood creatinine) may be changed by MULTAQ and may lead your doctor to take into account another reference for the “normal” value. Please notify any other doctor you may consult for the first time about your new "normal" value for your blood creatinine.

INTERACTIONS WITH THIS MEDICATION

MULTAQ can interact with certain other medicines and cause serious side effects.

Tell your doctor about all medicines you take. Keep a list of them with you at all times. Show it to your doctor and pharmacist each time you get a new medicine. Do not take any new medicines

while you are taking MULTAQ unless you have talked with your doctor. **Include all non-prescription medicines, vitamins, and herbal remedies.** MULTAQ and certain other medicines can interact with each other, causing serious side effects. Sometimes the dose of other medicines must be changed when they are used with MULTAQ.

Tell your doctor about:

- Water pills for high blood pressure. They could lower your blood potassium and magnesium.
- All heart medicines and blood pressure medicines
- Medicines for hay fever, cancer, or high cholesterol
- Medicines to treat infections, depression, or seizures
- Medicines used in organ transplants
- St. John’s Wort
- Medication for fungal infections

You should avoid:

Drinking grapefruit juice or eating grapefruit.

PROPER USE OF THIS MEDICATION

Usual dose:

Take MULTAQ as your doctor tells you at the same time each day.

Take 1 MULTAQ tablet (400 mg) 2 times a day with meals.

- Take the first MULTAQ tablet with your morning meal.
- Take the second MULTAQ tablet with your evening meal.

Keep taking MULTAQ even if you feel better. If you stop, your condition may get worse. Keep taking MULTAQ until your doctor tells you to stop. Make sure to observe all appointments with your doctor for check-ups.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or Regional Poison Control Centre immediately, even if there are no symptoms.

Taking too much MULTAQ can be dangerous. You may need medical care right away.

Missed Dose:

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 make up for a missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The common side effects are:

- digestive disturbances such as diarrhea, nausea, vomiting, abdominal pain and indigestion
- feeling tired and weak

Other side effects may also be observed:

- skin problems such as rash and itching redness of skin, eczema, inflammation of the skin, abnormal sensitivity of the skin to sunlight
- change in your sense of taste, loss of taste.

Talk with your doctor about any side effects that bother you. These are not all the side effects of MULTAQ. Your doctor and pharmacist have a more complete list.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptoms		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Diarrhea	√		
Uncommon	Nausea	√		
	Vomiting	√		
	Abdominal pain	√		
	Feeling tired and weak	√		
	Chest pain		√	
	Dizziness		√	
	Rash	√		
	Low heart beat		√	
	Swollen feet or legs, trouble breathing when lying down or sleeping, shortness of breath when moving around, or weight increase		√	
	Liver injury with symptoms such as: 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.		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptoms	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Respiratory symptoms such as: difficulty breathing, fatigue, and cough.		√	
Angioedema: swelling of the face, arms and legs, eyes, lips, tongue or difficulty swallowing or breathing			√

This is not a complete list of side effects. For any unexpected effects while taking MULTAQ, contact your doctor or pharmacist.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

HOW TO STORE IT

Keep MULTAQ and all other medications out of the reach and sight of children.

Keep the tablets in their original package and store at room temperature (15°-30°C).

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found on Health Canada's website (<http://hc-sc.gc.ca/index-eng.php>), at www.sanofi.ca, or by contacting the sponsor, sanofi-aventis Canada Inc., at:

1-800-265-7927

This leaflet was prepared by sanofi-aventis Canada Inc.

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