

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

Pr **MULTAQ<sup>®</sup>**

#### **Dronedarone Tablets**

Read this carefully before you start taking **MULTAQ** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MULTAQ**.

#### **What is MULTAQ used for?**

MULTAQ is used in adults who have atrial fibrillation (abnormal heart rhythm which is rapid and irregular) that:

- lasts less than a week (paroxysmal atrial fibrillation) or
- lasts longer than a week (persistent atrial fibrillation).

It is used in people who currently have a normal heart rhythm or are going to be converted to a normal heart rhythm. It helps lower the chances of having to go into the hospital for atrial fibrillation.

#### **How does MULTAQ work?**

MULTAQ helps prevent or correct irregular heartbeats and other heart rhythm problems by blocking multiple channels in the heart. It works through several mechanisms, including blocking potassium, sodium, and calcium currents, and reducing adrenergic activity.

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

Medicinal ingredient: dronedarone hydrochloride

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

#### **MULTAQ comes in the following dosage forms:**

Tablets: 400 mg dronedarone (as dronedarone hydrochloride)

#### **Do not use MULTAQ if:**

- you are allergic to dronedarone or to any of the other ingredients in MULTAQ;
- you have or have a history of heart failure;
- you have permanent atrial fibrillation (an abnormal heart rhythm which is fast and irregular) and cannot be corrected by treatments;
- you have left ventricular systolic dysfunction (a weakness to a part of the heart that pumps oxygen-rich blood to the rest of the body);
- you have bradycardia (abnormally slow heart beat);
- you have any of the following heart problems and do not have a functional pacemaker:
  - second or third degree heart block (a type of irregular heart beat and rhythm);
  - complete bundle branch block (a type of abnormal heart rhythm caused by something blocking the electrical signal that causes your heart to beat);
  - distal block (the heart's electrical signals are blocked, making it hard for the heart to pump blood);

- sinus node dysfunction (the heart's natural pacemaker is unable to create normal heartbeats at the normal rate).
- you have abnormal or unstable blood flow and blood pressure;
- you have a certain type of electrocardiogram (ECG) abnormality called QTc prolongation;
- you have liver or lung problems from using amiodarone;
- you take certain medicines that can change the amount of MULTAQ that gets into your body, such as:
  - ketoconazole;
  - itraconazole;
  - voriconazole;
  - cyclosporin;
  - clarithromycin;
  - ritonavir.
- you take certain medicines that can lead to torsade de pointes (a dangerous abnormal heart rhythm), such as:
  - phenothiazines;
  - antidepressants;
  - oral antibiotics;
  - certain medicines for abnormal heart rhythm or fast heartbeat.
- you have severe liver problems;
- you are pregnant or planning to become pregnant;
- you are breastfeeding or planning to breastfeed.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MULTAQ. Talk about any health conditions or problems you may have, including if you :**

- are taking blood thinners (medicines that help prevent blood clots from forming in veins and arteries), such as dabigatran or rivaroxaban;
- have any heart problems;
- have low levels of potassium or magnesium in your blood;
- have liver problems;
- are 75 years of age or older.

**Other warnings you should know about:**

Taking MULTAQ may cause the following:

- **Heart problems:** MULTAQ can cause other heart problems such as heart failure. Your healthcare professional may monitor your heart throughout treatment. They will interpret the results and may have you stop taking MULTAQ. Talk to your healthcare professional if you:
  - have unexplained weight gain;
  - swelling in the legs, feet or arms;
  - increasing shortness of breath.
- **Liver problems:** MULTAQ can cause liver problems including liver injury. Your healthcare professional may monitor your liver throughout treatment. They will interpret the results and may have you stop taking MULTAQ. Talk to your healthcare professional right away if you have:
  - loss of appetite;
  - nausea, vomiting;

- fever, feeling unwell, unusual tiredness;
- pain or discomfort in the right upper stomach area;
- yellowing of the skin or whites of the eyes (jaundice);
- dark urine;
- itching.

**Pregnancy and birth control:**

- MULTAQ should not be used during pregnancy. Taking it during pregnancy may cause injury to your baby.
- If you are a woman who could become pregnant, your healthcare professional will ask you to do a pregnancy test before you start taking MULTAQ.
- You should use an effective birth control (contraception) method during treatment and for 7 days after your final dose of MULTAQ.
- Tell your healthcare professional right away if you become pregnant or think you are pregnant during treatment with MULTAQ.

**Monitoring and testing:** During your treatment with MULTAQ, your healthcare professional may perform tests, such as blood tests and electrocardiogram tests, to:

- monitor the health of your liver, kidneys and heart;
- determine how long it takes for your blood to clot.

Your healthcare professional will interpret your results and may stop your treatment with MULTAQ.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**Serious Drug Interactions**

**Do not take MULTAQ if you are taking:**

- medicines that can change the amount of MULTAQ that gets into your body, such as:
  - ketoconazole and itraconazole, used to treat fungal infections;
  - ritonavir, used to treat HIV;
  - cyclosporin, used to treat organ rejection post-transplant;
  - clarithromycin, used to treat bacterial infections.
- medicines that can lead to torsade de pointe (a dangerous abnormal heart rhythm), such as:
  - phenothiazines, used to treat mental health problems and seizures;
  - medicines used to treat depression;
  - certain medicines used to treat bacterial infections;
  - medicines used to treat abnormal heart rhythms.

**The following may also interact with MULTAQ:**

- medicines known as beta-blockers used to treat high blood pressure (such as metoprolol and propranolol);
- medicines known as calcium antagonists used to help improve blood flow and reduce the workload on the heart (such as verapamil, diltiazem and nifedipine);
- digoxin, used to help the heart pump better and to control irregular heartbeats;

- erythromycin, used to treat bacterial infections in the body;
- medicines used to help prevent blood clots (such as dabigatran, rivaroxaban, edoxaban, apixaban, warfarin and other vitamin K antagonists);
- medicines known as P-glycoprotein (P-gp) substrates, including:
  - doxorubicin, used to treat cancer;
  - fexofenadine, used to relieve the symptoms of hay fever;
  - talinolol, used to treat high blood pressure.
- medicines known as potent CYP 3A4 inducers used to help breakdown and remove drugs (such as rifampicin, phenobarbital, carbamazepine and phenytoin);
- sirolimus and tacrolimus, used to help prevent organ rejection after transplant;
- medicines known as statins, used to lower high cholesterol in the blood (such as simvastatin, lovastatin, atorvastatin and pravastatin);
- theophylline, used to open up the airways in the lungs so it's easier to breathe;
- grapefruit juice. Do not drink grapefruit juice while you are taking MULTAQ;
- St John's Wort, an herbal compound commonly used to treat depression and mood disorders.

#### **How to take MULTAQ:**

- Take MULTAQ exactly as your healthcare professional tells you to. Do not stop taking MULTAQ without first talking to your healthcare professional.
- Take MULTAQ with a meal.

#### **Usual dose:**

Take one 400 mg tablet in the morning and one 400 mg tablet in the evening.

#### **Overdose:**

If you think you, or a person you are caring for, have taken too much MULTAQ, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

#### **Missed dose:**

If you missed a dose of this medication, you do not need to make up the missed dose. Skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

#### **What are possible side effects from using MULTAQ?**

These are not all the possible side effects you may have when taking MULTAQ. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- digestive problems (such as diarrhea, nausea, vomiting, stomach pain and indigestion);
- feeling tired or weak;
- skin problems (such as redness, rash, itching, inflammation and eczema);
- change to or loss of your sense of taste.

Serious side effects and what to do about them			
Symptom / effects	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Bradycardia (abnormally slow heartbeat)		√	
UNKNOWN FREQUENCY			
Acute Kidney Failure (severe kidney problems): confusion; itchiness or rashes; puffiness in your face and hands; swelling in your feet or ankles; urinating less or not at all; weight gain.		√	
Allergic Reaction: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat.			√
Arrhythmia (abnormal heart rhythms): rapid, slow or irregular heartbeat		√	
Congestive Heart Failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise		√	
Interstitial Lung Disease (diseases that inflame or scar lung tissue): shortness of breath when rest that gets worse with exertion, dry cough		√	
Liver Failure (serious disturbance of liver function, hepatic failure): yellow colour to skin, whites of the eyes (jaundice), bleeding easily, swollen abdomen, mental disorientation or confusion, sleepiness, coma		√	

Serious side effects and what to do about them			
Symptom / effects	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Liver Injury:</b> pain in the right abdomen, fever, fatigue, weakness, nausea, vomiting, loss of appetite, yellowing of the skin or eyes, dark urine		✓	
<b>Prolongation of QT Interval</b> (a heart rhythm condition): Irregular heartbeat, fainting, loss of consciousness, seizures		✓	
<b>Vasculitis</b> (inflammation of the blood vessels): fever, fatigue, weight loss, muscle and joint pain, loss of appetite, numbness, weakness		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

### Storage:

Store MULTAQ at room temperature, between 15°C and 30°C.

Keep MULTAQ in its original packaging.

Keep out of reach and sight of children.

### If you want more information about MULTAQ:

- Talk to your healthcare professional

- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.sanofi.ca](http://www.sanofi.ca), or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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