

MULTAQ[®]

Dronedarone 400 mg

What is in this leaflet

1. What Multaq is used for
2. How Multaq works
3. Before you use Multaq
4. How to take Multaq
5. While you are using it
6. Side effect
7. Storage and disposal of Multaq
8. Product description
9. Manufacturer and product registration holder
10. Date of revision

What Multaq is used for

Multaq contains an active substance named dronedarone.

Multaq is used to maintain the normal heart beat after successful cardioversion in adult with atrial fibrillation (an abnormal heart rhythm).

How Multaq works

Multaq belongs to a group of medicines called anti-arrhythmics. It regulates your heart beat and prevents repetition of your irregular heart beat problem.

Before you use Multaq**When you must not use it**

Do not take Multaq if:

- you are allergic to dronedarone or to any of the other ingredients of this medicine (listed in Product description),
- you have a problem with the nerves in your heart (heart block). Your heart might beat very slowly or you may feel dizzy. If you have had a pacemaker fitted for this problem, you can use Multaq,
- you have a very slow heart beat (less than 50 beats a minute),
- your ECG (electrocardiogram), shows a heart problem called “prolonged QT corrected interval” (this interval is more than 500 milliseconds),
- you have a type of atrial fibrillation called permanent atrial fibrillation (AF).

- you have or had a problem where your heart cannot pump the blood round your body as well as it should (condition called heart failure). You may have swollen feet or legs, trouble breathing when lying down or sleeping, or shortness of breath when moving around,
 - the percentage of blood leaving your heart each time it contracts is too low (condition called left ventricular dysfunction),
 - you took amiodarone previously and experienced lung or liver problems,
 - you are taking other medicine listed under “Taking other medicines”,
 - you have a severe liver problem,
 - you have a severe kidney problem,
- If any of the above apply to you, do not take Multaq.

Before you start to use it

Talk to your doctor or pharmacist before taking Multaq if

- you have a problem that gives you a low level of potassium or magnesium in your blood. This problem should be corrected before starting treatment with Multaq,
- you are more than 75 years old,
- you have a condition when the vessel that supplies blood to heart muscle becomes hardened and narrowed (coronary artery disease).

Multaq contains lactose

Multaq contains lactose, which is a type of sugar. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking Multaq.

Taking other medicines

Your doctor may recommend that you use a medicine against blood clot formation according to your condition. Multaq and some other medicines can affect each other and cause serious side effects. Your doctor may change the dose of any other medicines you are taking. You must not take any of the following with Multaq:

- other medicines used to control an irregular or fast heart beat such as flecainide, propafenone, quinidine, disopyramide, dofetilide, sotalol, amiodarone,
- some medicines for fungal infections such as ketoconazole, voriconazole, itraconazole or posaconazole,
- some medicines for infections called macrolides (telithromycin, erythromycin, or clarithromycin),
- some medicines for depression called tricyclic antidepressants,
- some tranquilising medicines called phenothiazines,
- bepridil for chest pain caused by heart disease,
- terfenadine - for allergies,
- nefazodone - for depression,
- cisapride - for food and acid reflux from your stomach to your mouth,
- ritonavir - for AIDS infection,
- dabigatran – for prevention of blood clot formation.

You must tell your doctor or pharmacist if you are taking any of the following medicines:

- other medicines for high blood pressure, for chest pain caused by heart disease, or other heart problems, such as verapamil, diltiazem, nifedipine, metoprolol, propranolol or digoxin,
- some medicines for reducing the cholesterol in your blood (such as simvastatin, lovastatin, atorvastatin, rosuvastatin, or pravastatin),
- some medicines against blood clot formation such as warfarin,
- some medicines for epilepsy called phenobarbital, carbamazepine or phenytoin,
- sirolimus, tacrolimus, everolimus and cyclosporine (used after a transplant),
- St John’s Wort - a herbal medicine for depression,
- rifampicin - for tuberculosis.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

How to use Multaq

Always take this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

If you need to change from amiodarone (another medicine for irregular heart beat) to Multaq, your doctor will handle such change with caution.

How much to use

The usual dose is one 400 mg tablet twice a day. Take:

- one tablet during your morning meal and
 - one tablet during your evening meal.
- If you think that your medicine is too strong or too weak, talk to your doctor or pharmacist.

When to take it

Swallow the tablets whole with a drink of water during a meal.

Do not drink grapefruit juice while taking Multaq. It can interfere with the usual effect of your medicine.

How long to take it

Continue taking your medicine for as long as your doctor continues to prescribe it.

Please talk to your doctor before you consider stopping treatment.

If you forget to take it

Do not take a double dose to make up for a forgotten tablet.

Take the next dose when you are normally due to take it

If you take too much (overdose)

Contact immediately your doctor or the nearest emergency department or hospital. Take the medicine pack with you.

While you are using it

Things you must do

While taking Multaq, Tell your doctor if

- your atrial fibrillation becomes permanent while you are taking Multaq. You should stop taking Multaq,

- you have swollen feet or legs, trouble breathing when lying down or sleeping, shortness of breath when moving around, or weight increase,
 - tell your doctor immediately if you develop any of these signs and symptoms of liver problems: Stomach (abdominal) area pain or discomfort, loss of appetite, nausea, vomiting, yellowing of the skin or the whites of the eyes (jaundice), unusual darkening of the urine, fatigue (especially in association with other symptoms listed above), itching,
 - you have breathlessness or non-productive cough. Tell your doctor, he/she will check your lung.
- If this applies to you (or you are not sure), please talk to your doctor or pharmacist.

Heart and blood tests

While you are taking Multaq, your doctor may perform tests to check your medical condition and how the medicine is working for you.

- Your doctor may look at your heart's electrical activity using an ECG (electrocardiogram) machine.
- 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.
- Your doctor may also do other blood tests. The results of one of the blood tests (blood creatinine levels) may be changed by Multaq. Please tell any other person who checks your blood that you are taking Multaq.

Things you must not do

Children and adolescent

Multaq is not recommended in children and adolescents below 18 years of age.

Pregnancy, breast-feeding and fertility

- Multaq is not recommended if you are pregnant or you think you may be pregnant.
- Do not take Multaq if you are a woman able to have children and you are not using a reliable contraceptive method.
- Stop taking your tablets and talk to your doctor straight away if you get pregnant while taking Multaq.

- If you are a mother breast-feeding a baby, you should discuss with your doctor before taking Multaq.

- Do not give this medicine to anyone else, even if they have the same condition as yours.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Multaq, or change the dosage, without checking with your doctor.

Things to be careful of

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

Side Effect

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported with this medicine:

Very Common (may affect more than 1 in 10 people)

- changes in the results of one blood test: your blood creatinine level,
- changes in your ECG (electrocardiogram),
- problem where your heart does not adequately pump the blood round your body as well as it should (congestive heart failure), which can cause shortness of breath or ankle swelling.

In clinical studies, this undesirable effect was observed at a similar rate in patients receiving MULTAQ and in patients receiving placebo.

Common (may affect up to 1 in 10 people)

- problems with your digestion such as diarrhoea, nausea, vomiting and stomach pain,
- feeling tired,
- slow heartbeat,
- skin problems such as rash or itching,
- change in the results of blood tests used to check your liver function.

Uncommon (may affect up to 1 in 100 people)

- other skin problems such as redness of the skin or eczema (redness, itching, burning or blistering),
- your skin being more sensitive to the sun,
- change in how things taste,
- inflammation of the lungs (including scarring and thickening of the lungs).

Rare (may affect up to 1 in 1,000 people)

- losing your sense of taste,
- liver problems including life threatening liver failure,
- allergic reactions, including swelling of the face, lips, mouth, tongue or throat.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Multaq

Storage

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the carton after “EXP.” The expiry date refers to the last day of that month.
- Store below 30°C.
- Do not use this medicine if you notice any visible sign of deterioration.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description

What it looks like

Multaq is a white, oval, film-coated tablet with a double wave marking on one side and “4142” on the other side.

Multaq film-coated tablets are supplied in packs of 20, 50, 60, 100 tablets in blisters. Not all pack size may be marketed.

Ingredients:

- The active substance is dronedarone. Each film-coated tablet contains 400 mg of dronedarone (as hydrochloride).
- The other ingredients in the film-coated tablet core are hypromellose, maize starch, crospovidone, poloxamer 407, lactose monohydrate, colloidal anhydrous silica, magnesium stearate.
- The other ingredients in the coating of the film-coated tablets are hypromellose, macrogol 6000, titanium dioxide (E171), carnauba wax.

MAL Numbers:

Multaq 400mg Film-coated Tablet:
MAL 20102016A

Manufacturer and Product Registration Holder

Manufacturer

Sanofi Winthrop Industrie
1, rue de la Vierge
Ambares et Lagrave
33565 Carbon Clanc Cedex
France

Product Registration Holder:

Sanofi-aventis (Malaysia) Sdn. Bhd.
Unit TB-18-1, Level 18, Tower B,
Plaza 33
No.1 Jalan Kemajuan,
Seksyen 13,
46200 Petaling Jaya,
Selangor Darul Ehsan,
Malaysia.

Date of revision

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