PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

MULTAQ
Film-Coated Tablets 400 mg

SANOFI

Active ingredient
Each film-coated tablet contains Dronedarone (as hydrochloride) 400 mg
For information on inactive and allergenic ingredients in the preparation: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".
Read this leaflet carefully in its entirety before using the medicine.
Keep this leaflet; you may need to read it again.
This leaflet contains concise information about the medicine.
If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is used for the treatment of atrial fibrillation after restoration of a normal heart rhythm (sinus rhythm).
Therapeutic group: An antiarrhythmic preparation for regulation of heart rhythm.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see section 6)
- You suffer from nerve conduction disturbances in the heart, manifested by a slow heart rate or dizzy feeling. If you have a pacemaker, you can use Multaq
- You suffer from a very slow heart rate (less than 50 beats per minute)
- The ECG shows a heart problem called "prolonged QT interval" (above 500 milliseconds)
- You suffer from chronic atrial fibrillation (fibrillation that persists continuously for at least 6 months) and a decision has been reached not to restore sinus rhythm by cardioversion
- You are suffering from unstable (drops in) blood pressure, which may cause inadequate arterial blood flow to the organs of the body
- You are suffering, or have suffered in the past, from heart failure that may be manifested by edema of the legs, breathing difficulties when lying down or sleeping or by shortness of breath when moving
- The volume of blood flowing from the heart with each contraction is too low (left ventricular dysfunction)
- You took amiodarone in the past and developed lung or liver side effects
- You are taking medicines for treatment of infections (including fungal infections or AIDS), allergy, heart rate problems, depression, medicines following a transplant (see section "Drug interactions")
- You suffer from severe liver function problems
- You suffer from severe kidney function problems
- You are taking dabigatran (to prevent formation of blood clots) (see section "Drug interactions")
- You are pregnant

If any of the above apply to you, do not take Multaq.

Special warnings regarding use of this medicine
Before treatment with Multaq, tell the doctor if:
- You suffer from a problem that leads to low blood levels of potassium or magnesium. This problem must be treated before starting to use Multaq
- You are more than 75 years old
- You suffer from a condition in which the blood vessel that supplies blood to the cardiac muscle becomes hardened and narrow (coronary heart disease)

During the course of treatment with the medicine, tell the doctor if:
- Your atrial fibrillation has become chronic under Multaq treatment - discontinue treatment with Multaq
- You have swelling in your feet or legs, difficulty breathing while lying down or sleeping, shortness of breath during activity or weight gain (these are signs and symptoms of heart failure)
- Tell the doctor immediately if you develop any of the following signs or symptoms of a liver problem: stomach (abdominal) area pain or discomfort, loss of appetite, nausea, vomiting, yellowing of the skin or the whites of the eyes (jaundice), unusually dark urine, fatigue (especially in combination with other symptoms described here), itching
- You suffer from breathlessness or a dry cough. Tell the doctor so he/she will check your lungs

If the above applies to you (or when in doubt), please consult the doctor or pharmacist before taking Multaq.
Tests and follow-up:
While using Multaq, the doctor may perform tests to check your medical condition and the effect of the medicine on you.
- The doctor may check your heart's electrical activity using an ECG (electrocardiogram) machine
- The doctor will send you for a blood test for liver function before starting treatment with Multaq and during the course of treatment
- If you are taking anticoagulants, such as warfarin, the doctor will send you for a blood test called INR, to check if the medicine is working well
- The doctor may also perform additional blood tests. The results of one of the tests to check kidney activity (blood creatinine levels) may be affected by Multaq. Your doctor will take this into account when checking the results of the blood tests and will use another reference for the "normal" value
- Your doctor may perform a lung test for you

In some cases it will be necessary to stop treatment with Multaq.
Please inform the person who checks your blood test results that you are taking Multaq.
Children and adolescents:
Multaq is not recommended for children and adolescents below 18 years of age.
Drug interactions:
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Your doctor may recommend the use of an anticoagulant, depending on your condition.
Multaq and other medicines may affect each other and cause serious side effects. The doctor may change the dosage of the other medicines you are taking.

Do not take any of the following medicines with Multaq:
- other medicines used to treat heart rhythm disturbances, such as: flecainide, propafenone, quinidine, disopyramide, dofetilide, sotalol, amiodarone
- medicines for treatment of fungal infections, such as: ketoconazole, voriconazole, itraconazole or posaconazole
- tricyclic antidepressants (for treatment of depression)
- medicines from the phenothiazine group (tranquilizers)
- bepridil for chest pain caused by heart disease
- telithromycin, erythromycin or clarithromycin (antibiotics for treatment of infections)
- terfenadine – to treat allergy
- nefazodone – to treat depression
- cisapride – to treat food and acid reflux from the stomach to the mouth
- ritonavir – to treat AIDS infection
- dabigatran – for prevention of formation of blood clots

Inform the doctor or pharmacist if you are taking any of the following medicines:
- medicines for treatment of high blood pressure, for chest pain caused by heart disease, or for other heart problems, such as: verapamil, diltiazem, nifedipine, metoprolol, propranolol or digoxin
- medicines for reducing the cholesterol in the blood, such as: simvastatin, lovastatin, atorvastatin or rosuvastatin
- medicines against blood clot formation, such as warfarin, ribroxaban, edoxaban and apixaban
- medicines for treatment of epilepsy: phenobarbital, carbamazepine or phenytoin
- medicines to prevent transplant rejection: sirolimus, tacrolimus, everolimus, cyclosporine
- a herbal preparation to prevent depression – St. John's wort (Hypericum)
- rifampicin – for tuberculosis

Use of the medicine and food:
Take one tablet with food in the morning and one tablet with food in the evening.

Do not drink grapefruit juice while taking Multaq as it can increase the level of the active ingredient, dronaderone, in the blood, and increase the risk of side effects.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor.

Do not take Multaq if you are pregnant or if you think you may be pregnant.

Do not take Multaq if you are of child-bearing age and do not use effective contraceptives.

If you become pregnant while using Multaq, stop taking the tablets and refer to the doctor immediately!

It is not known whether Multaq passes into breast milk. Consult the doctor to decide whether to use Multaq or to breastfeed. You will not be able to do both.

Consult the doctor or pharmacist before taking any medicine during pregnancy or while breastfeeding.

Driving and operating machinery:

Multaq usually does not affect the ability to drive or to use machines. However, your ability to drive or to use machines may be affected by side effects, such as tiredness.

Important information about some of the ingredients of the medicine:
Multaq contains lactose.

Lactose is a type of sugar. If you have been told by your doctor that you suffer from an intolerance to certain sugars, refer to your doctor before commencing treatment with this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

If you have to switch from treatment with amiodarone (another medicine for treatment of arrhythmias) to treatment with Multaq, perform this change with caution.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally one Multaq 400 mg tablet, twice a day:

- One tablet in the morning, with breakfast
- One tablet in the evening, with dinner
- If you think the medicine is too strong or too weak, tell the doctor or pharmacist

Method of administration:

Swallow the tablet whole with water during the meal. There is no information regarding crushing/halving/chewing the tablet.

Do not exceed the recommended dosage.

If you accidentally took a higher dosage:

Refer immediately to your doctor or proceed to the closest emergency room. Bring the package of the medicine with you.

If you forget to take the medicine:

If you forgot to take this medicine at the regular time, take a dose at the next usual dosing time. Never take a double dose to compensate for the forgotten dose!

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine:

Do not stop using the medicine without consulting a doctor or pharmacist, even if there is an improvement in your health.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Multaq may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

The following side effects have been reported while using this medicine:

Talk to your doctor straight away, if you notice any of the following serious side effects – you may need urgent medical assistance

Very common side effects (may occur in more than 1 user in 10):

- heart failure. In clinical trials this effect was observed at the same frequency in patients who received Multaq as in patients who received a placebo. Signs of this include swelling of the feet or legs, breathing difficulties when lying down or sleeping, shortness of breath when active, weight gain

Common side effects (may occur in 1-10 users in 100):

- diarrhea and frequent vomiting may lead to kidney problems
- slow heart rate

Uncommon side effects (may occur in 1-10 users in 1,000):

- inflammatory lung disease (including scarring and thickening of the lungs). Signs of this include shortness of breath or nonproductive cough

Rare side effects (may occur in 1-10 users in 10,000):

- liver problems, including life-threatening liver damage. The signs include: pain or discomfort in the stomach (abdominal) area, loss of appetite, nausea, vomiting, yellowing of the skin or the whites of the eyes (jaundice), darker urine than usual, fatigue (especially in combination with other symptoms described here), itching
- an allergic reaction, including swelling of the face, lips, mouth, tongue and throat

Additional side effects:

Very common side effects:

- changes in the results of one blood test: your blood creatinine level
- change in ECG test result (QTc Bazett prolonged)

Common side effects:

- digestive system problems, such as: diarrhea, nausea, vomiting and abdominal pain
- feeling tired
- skin problems such as rash or itching
- change in the results of blood tests used to check your liver function

Uncommon side effects:

- other skin problems, such as skin redness or eczema (redness, itching, burning sensation or blisters)
- increased skin sensitivity to sun exposure
- change in sense of taste

Rare side effects:

- loss of sense of taste
- inflammation of the blood vessel wall (vasculitis including leukocytoclastic vasculitis)

If one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning.

Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package/tray (blister). The expiry date refers to the last day of that month.

Storage: Store below 30°C.

6. FURTHER INFORMATION

In addition to the active ingredient, Multaq also contains:

Crospovidone (type A), maize starch, lactose monohydrate (41.65 mg), poloxamer 407, hypromellose, magnesium stearate, colloidal anhydrous silica, macrogol 6000, titanium dioxide (E171), carnauba wax.

What does the medicine look like and what are the contents of the pack:

The tablets are packaged in a tray pack (blister).

Multaq are oval, film-coated, white tablets, with a double wave marking on one side and "4142" on the other side.

The tablets are packaged in PVC/aluminium trays (blisters) of 10, 14, 20, 28, 30, 50 or 60 tablets.

Not all package sizes are marketed.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, please ask your doctor.

License holder and address: sanofi-aventis Israel ltd., 10 Beni Gaon Street, Netanya.

Manufacturer and address: Sanofi Winthrop Industrie, France.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1424232977