



EUROPEAN MEDICINES AGENCY  
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## EPAR summary for the public

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# Multaq

dronedarone

This is a summary of the European public assessment report (EPAR) for Multaq. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Multaq.

For practical information about using Multaq, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Multaq and what is it used for?

Multaq is an antiarrhythmic medicine used to maintain normal heart rhythm in adults whose normal heart rhythm has been restored after a period of paroxysmal or persistent atrial fibrillation. Atrial fibrillation is when the atria (the upper chambers of the heart) contract irregularly and rapidly, and this abnormality can be short-lasting (paroxysmal) or it can last longer than a few days (persistent).

Multaq should only be prescribed after alternative treatment options have been considered.

Multaq should not be given to patients with left ventricular systolic dysfunction (a problem affecting the left side of the heart) or patients who have or have had heart failure (when the heart cannot pump enough blood around the body).

Multaq contains the active substance dronedarone.

## How is Multaq used?

Multaq can only be obtained with a prescription and treatment with it should be started and monitored under specialist supervision.

Multaq is available as tablets (400 mg) and the recommended dose is one tablet twice a day, with the morning and evening meals.



## How does Multaq work?

The active substance in Multaq, dronedarone, works mainly by blocking channels through which charged particles of potassium flow in and out of the heart muscle cells. Increased flow of charged particles produces the excessive electrical activity that leads to atrial fibrillation and rapid heart rate. By reducing the flow of potassium through the channels, Multaq slows down contractions in the atria and so prevents fibrillation and lowers the heart rate.

## What benefits of Multaq have been shown in studies?

There were six main studies of Multaq in adults who had had atrial fibrillation.

The first three studies, involving, 1,411 patients, found that Multaq was more effective than placebo (a dummy treatment) at preventing atrial fibrillation. The main measure of effectiveness was how long the treatment prevented an attack of atrial fibrillation or the change in the patients' heart rate after two weeks. Multaq prevented fibrillation for an average of 116 days compared to 53 days with placebo. Heart rate was reduced by an average of 11.0 beats per minute in patients taking Multaq compared to 0.7 beats per minute in patients taking placebo.

The fourth study compared Multaq with amiodarone (another medicine used to prevent atrial fibrillation) in 504 patients. Multaq was less effective than amiodarone at maintaining normal rhythm: after a year, atrial fibrillation came back or treatment was stopped in 75% of the patients taking Multaq, compared with 59% of the patients receiving amiodarone. However, more patients taking amiodarone had to stop treatment because of side effects.

The fifth study compared Multaq with placebo in almost 5,000 patients. It gave further support for the use of Multaq to maintain normal heart rhythm and to reduce the heart rate. The study found that in patients taking Multaq, there were fewer hospital admissions for cardiovascular disorders (problems affecting the heart and blood vessels), particularly those related to atrial fibrillations.

A sixth study (PALLAS) compared Multaq with placebo in patients over 65 years of age with permanent atrial fibrillation and several risk factors. The study was stopped early because of severe cardiovascular events (such as cardiovascular death or hospitalisation and stroke) in some patients taking Multaq.

## What are the risks associated with Multaq?

The most common side effects with Multaq (seen in more than 1 patient in 10) are increased blood levels of creatinine (a breakdown product of muscle), a prolonged 'QTc Bazett' (an alteration of the electrical activity of the heart) and congestive heart failure (a type of heart disease), but this side effect occurred at a similar rate in patients who took placebo in clinical studies. For the full list of all side effects reported with Multaq, see the package leaflet.

Multaq must not be taken with medicines that can cause torsades de pointes (a type of rapid heart beat), or with dabigatran (a medicine to prevent blood clotting). It must not be used in patients with permanent atrial fibrillation of unknown duration or lasting for more than six months when the doctor has decided not to try to restore normal rhythm. It must also not be used in patients with some other heart problems, such as some problems with the electrical activity, very slow heart beats or heart failure.

Multaq must not be used in patients who have severe problems with their liver or kidneys. Patients who have had previous liver or lung injury following treatment with amiodarone (another anti-arrhythmic medicine) must not be given Multaq. For the full list of restrictions, see the package leaflet.

## Why is Multaq approved?

Based on the available evidence, the CHMP decided that Multaq's benefits are greater than its risks and recommended that Multaq be given marketing authorisation.

Multaq was originally approved to prevent atrial fibrillation from coming back or to lower the heart rate in adults who have had or have non-permanent atrial fibrillation. In September 2011 this indication was restricted to the maintenance of normal heart rhythm in 'persistent' or 'paroxysmal' atrial fibrillation after normal heart rhythm has been restored. This followed a review of data that became available since its authorisation including data from the PALLAS study.<sup>1</sup>

## What measures are being taken to ensure the safe use of Multaq?

The company that makes Multaq must ensure that healthcare professionals who prescribe and dispense the medicine in all Member States are given a 'prescriber guide'. The prescriber guide will help healthcare professionals to use Multaq safely and to select patients for whom it is appropriate. The guide will also include information on: when not to use Multaq; medicines that interact with Multaq; the need to monitor the function of the liver, lung, heart and kidneys before and during treatment; and what advice to give to patients on Multaq treatment.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Multaq have also been included in the summary of product characteristics and the package leaflet.

## Other information about Multaq

The European Commission granted a marketing authorisation valid throughout the European Union for Multaq on 26 November 2009.

The full EPAR for Multaq can be found on the Agency's website [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_Public\\_Assessment\\_Reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports). For more information about treatment with Multaq, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2016.

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<sup>1</sup> In the context of a procedure under Article 20 of Regulation (EC) No 726/2004.