



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2012
EMA/CHMP/603654/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

MULTAQ

dronedarone

On 20 September 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product MULTAQ. The marketing authorisation holder for this medicinal product is Sanofi. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new contraindication as follows:
"Co-administration with dabigatran".

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full contraindication(s) for MULTAQ will be as follows²:

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Second- or third- degree Atrio-Ventricular block, complete bundle branch block, distal block, sinus node dysfunction, atrial conduction defects, or sick sinus syndrome (except when used in conjunction with a functioning pacemaker).
- Bradycardia <50 beats per minute (bpm)
- Permanent AF with an AF duration ≥ 6 months (or duration unknown) and attempts to restore sinus rhythm no longer considered by the physician
- Patients in unstable hemodynamic conditions,
- History of, or current heart failure or left ventricular systolic dysfunction

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

² The text in bold represents the new or the amended contraindication.



- Patients with liver and lung toxicity related to the previous use of amiodarone
- Co-administration with potent cytochrome P 450 (CYP) 3A4 inhibitors, such as ketoconazole, itraconazole, voriconazole, posaconazole, telithromycin, clarithromycin, nefazodone and ritonavir (see section 4.5)
- Medicinal products inducing torsades de pointes such as phenothiazines, cisapride, bepridil, tricyclic antidepressants, terfenadine and certain oral macrolides (such as erythromycin), Class I and III antiarrhythmics (see section 4.5)
- QTc Bazett interval ≥ 500 milliseconds
- Severe hepatic impairment
- Severe renal impairment (CrCl < 30 ml/min)
- **Co-administration with dabigatran**