MULTAQ Prescribing Information

See Summary of Product Characteristics before prescribing.

Presentation: White, oblong shaped tablets containing 400mg dronedarone. **Indication:** Use in adult clinical stable patients with a history of, or current non-permanent atrial fibrillation (AF) to prevent recurrence of AF or to lower ventricular rate. **Dosage:** Adults and Elderly: 400mg twice daily, one tablet with the morning meal and one tablet with the evening meal. Not recommended under 18 years. **Contraindications:** Hypersensitivity to dronedarone or excipients; second or third degree atrio-ventricular block or sick sinus syndrome (except when used with a functioning pacemaker); bradycardia < 50 beats per minute; unstable haemodynamic conditions including patients with symptoms of heart failure at rest or with minimal exertion (corresponding to NYHA Class IV and unstable Class III patients); co-administration with cytochrome P450 (CYP) 3A4 inhibitors (such as ketoconazole, itraconazole, voriconazole, posaconazole, telithromycin, clarithromycin, nefazodone and ritonavir); co-administration with products inducing torsades de pointes (such as phenothiazines, cisapride, bepridil, tricyclic antidepressants, terfenadine and certain oral macrolides (such as erythromycin), Class I and III anti-arrhythmics); QTc Bazett interval ≥ 500 milliseconds; severe hepatic impairment; severe renal impairment (CrCL < 30ml/min). **Warnings:** Not recommended in stable patients with recent (1 to 3 months) NYHA Class III heart failure or Left Ventricular Ejection Fraction < 35%. Patients should be advised to consult a physician if they develop or experience worsening signs or symptoms of heart failure, discontinuation of Multaq may need to be considered if heart failure develops. Liver function tests should be performed prior to initiation of treatment with dronedarone and then repeated monthly for 6 months, at months 9 and 12, and periodically thereafter. If ALT (alanine aminotransferase) levels are elevated ≥3 x upper limit of normal (ULN), ALT levels should be re-measured within 48 to 72 hours. If ALT levels are confirmed to be ≥3 x ULN, treatment should be discontinued. Appropriate investigation and close observation of patients should continue until normalisation of ALT. Measure creatinine clearance values 7 days after initiating dronedarone and use these as the new reference baseline, as in increase in creatininemia may be expected. An increase in creatininemia should not necessarily lead to the discontinuation of treatment with ACE inhibitors or Angiotensin II Receptor Antagonists (AIIRAs). Correct any potassium or magnesium deficiency before initiation and during treatment. The pharmacological action of dronedarone may induce a moderate QTc Bazett prolongation (about 10 msec). These changes do not reflect toxicity. Follow up, including ECG (electrocardiogram), is recommended during treatment. If QTc Bazett interval is ≥ 500 milliseconds, dronedarone should be stopped. Dronedarone has a low pro-arrhythmic effect; however, proarrhythmic effects may occur in particular situations such as concomitant use with medicinal products favouring arrhythmia and/or electrolytic disorders. Patients with galactose intolerance should not take dronedarone as it contains lactose. Not recommended in pregnancy. Individual clinical assessment needed in lactation. **Drug Interactions:** Contraindicated with products inducing torsades de pointes and potent CYP 3A4 inhibitors. Not recommended with potent CYP3A4 inducers such as rifampicin, phenobarbital, carbamazepine, phenytoin or St John's Wort. Concomitant use with dabigatran is not recommended due to dronedarone increasing the exposure of dabigatran. Patients should be warned to avoid grapefruit juice beverages while taking dronedarone. Caution when used with calcium antagonists and beta-blockers (if initiating either, start at the lowest dose and increase according to ECG response; if established on treatment, monitor with ECG and adjust dose(s) as necessary), statins (consider lower starting and maintenance doses and monitor for signs of muscle toxicity), sirolimus, tacrolimus, and digoxin (digoxin dose should be reduced by approximately 50%). No interactions observed with oral contraceptives, warfarin, theophylline, antidepressants, metformin, omeprazole, clopidogrel, pantoprazole or losartan. **Side Effects (see SPC for full details):** Nervous system disorders: dysgeusia (uncommon), aguesia (rare); Cardiac disorders: Congestive heart failure (very common), bradycardia (common); Gastrointestinal disorders: diarrhoea, nausea, vomiting, abdominal pains, dyspepsia (common); Hepatobiliary disorders: Liver function test abnormalities (common), hepatocellular liver injury, including life-threatening acute liver failure (rare); Skin and subcutaneous disorders: rashes and pruritus (common), erythemas, eczema, photosensitivity, dermatitis – including allergic (uncommon); General disorders: fatigue, asthenia (common); Investigations: increased blood creatinine, prolonged QTc Bazett (very common). **Legal category:** POM. **Product Licence Numbers:** EU/1/09/591/001 (400mg tablets – 20 pack size) EU/1/09/591/003 (400mg tablets – 60 pack size) **Marketing authorisation Holder:** sanofi-aventis, 174, avenue de France, F-75013 Paris, France. Further information is available from: sanofi-aventis, One Onslow Street, Guildford, Surrey, GU1 4YS Tel: 01483 505515 Fax: 01483 535432. **Basic NHS Price:** £22.50 for 20 tablet pack; £67.50 for 60 tablet pack. **Date of preparation:** August 2011.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk.

Adverse events should also be reported to the sanofi-aventis drug safety department on 01483 505515.

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