Make a date for our symposium at the Heart Rhythm Congress

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Sanofi sponsored symposium

The Impact of New 2012 Atrial Fibrillation Guidelines on the Use of Anti-arrhythmic Drugs

Date: Monday, 24th September 2012

Time: 08:30–10:00

Venue: Hall 9, The ICC, Birmingham

Chair: Dr Derick Todd
Consultant Cardiologist
Liverpool Heart and Chest Hospital

Speakers:

Professor John Camm
Professor of Clinical Cardiology
St George's Hospital, London

ESC & Canadian AF guidelines: how have they changed?

Professor Camm will provide an update on recent amendments to various European and Canadian atrial fibrillation guidelines and outline on how these may be interpreted in the UK.

Professor Paulus Kirchhof
Chair in Cardiovascular Medicine
University of Birmingham

Anti-arrhythmic drugs: patient selection and drug safety

Professor Kirchhof will outline his views on how patient selection should be viewed in context of the new clinical guidelines and the importance of drug safety when using AADs.

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MULTAQ™ dronedarone

MULTAQ Prescribing Information
See Summary of Product Characteristics before prescribing.

Presentation: White, oblong shaped tablets containing 400mg Multaq. **Indication:** Maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation (AF). Multaq should only be prescribed after alternative treatment options have been considered. Multaq should not be given to patients with left ventricular systolic dysfunction or to patients with current or previous heart failure. **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 Multaq 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; permanent AF with an AF duration ≥ 6 months (or unknown duration) and attempts to restore sinus rhythm no longer considered by physician; unstable haemodynamic conditions; history of, or current heart failure or left ventricular systolic dysfunction; use in patients with liver and lung toxicity related to the previous use of amiodarone; 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:** Caution is needed in patients who are ≥ 75 years old when co-morbities are present. Careful regular monitoring of cardiac, hepatic and pulmonary function should be conducted during Multaq administration. If AF reoccurs discontinuation of Multaq should be considered. Treatment with Multaq should be stopped if the patient develops any conditions that would lead to a contraindication. ECGs should be performed serially, at least every 6 months. If patients develop permanent AF whilst on Multaq, treatment should be discontinued. Patients should be carefully evaluated for symptoms of congestive heart failure or the development of left ventricular systolic dysfunction. If heart failure or left ventricular systolic dysfunction develops, Multaq should be discontinued. Caution is needed in patients with coronary artery disease. Liver function tests should be performed prior to initiation of treatment with Multaq 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 prior to and 7 days after initiating Multaq. If no further creatinaemia is observed, these values should be used as the new reference baseline. If creatinaemia continues to rise consideration should be given to further investigation and discontinuing treatment. 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 Multaq 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, Multaq should be stopped. Multaq 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 should be carefully monitored for pulmonary toxicity. Confirmation of pulmonary toxicity should lead to Multaq discontinuation. Patients with galactose intolerance should not take Multaq 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 Multaq increasing the exposure of dabigatran. Patients should be warned to avoid grapefruit juice beverages while taking Multaq. Monitoring of co-administered drugs like digoxin and anticoagulants is necessary. Clinical, ECG and biological monitoring are recommend when concomitantly administered with digoxin, and the does of digoxin should be halved. Caution when used with calcium antagonists and beta-blockers with a depressant effect on sinus and atrio-ventricular node (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). When using Multaq with: statins, consider lower starting and maintenance doses and monitor for signs of muscle toxicity; sirolimus and tacrolimus, monitoring of plasma concentrations and appropriate dose adjustments is recommended. INR should be closely monitored after initiating Multaq in patients taking vitamin K antagonists. No interactions observed with oral contraceptives, 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); Respiratory, thoracic and mediastinal disorders: Interstitial lung disease, including pneumonitis and pulmonary fibrosis; 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, 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:** July 2012

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard
Adverse events should also be reported to the Sanofi drug safety department on 01483 505515.

GBIE.DRO.12.08.01f
Date of preparation: August 2012