



## Tayside DTC Supplement No 113 – January 2012

Produced by NHS Tayside Drug and Therapeutics Committee Medicines Advisory Group (MAG)

### Special points of interest for Primary Care

- Citalopram / Escitalopram - QT interval prolongation

#### SMC advice:

- Apixiban (Eliquis®)
- Denosumab (Xgeva®)
- Dexamethasone (Ozurdex®)
- Telaprevir (Incivo®)
- Alteplase (Actilyse Cathflo®)
- Dronedarone (Multiaq®)
- Ticagrelor (Brilique®)



## Specialist lists - update

The development of specialist formulary lists started in January 2011 and the majority of specialist lists should be completed by the end of 2012. The aim is to increase the relevance of the formulary to secondary care and improve formulary compliance.

It is hoped that the specialist lists will give clear guidance on specialist medicines or medicines initiated by specialists and make it easier for prescribers to find relevant protocols and guidance on use of specialist hospital medicines.

Click on the links below to see copies of the completed specialist lists: [Cardiology](#); [Chronic Pain](#); [ENT](#); [Oncology & Haematology Protocols](#); [Palliative Care](#); [Renal](#); [Respiratory](#); [Rheumatology](#) and [Stroke](#).

Urology should be finalised next month and work is ongoing to finalise the Endocrinology, Gastroenterology, Mental Health and Psychiatry of Old Age specialist lists.

For further information on the timescales for the development of specialist lists [Click Here](#)



## Guidelines and Protocols

### Dronedarone (Multiaq®▼) – updated protocol

Further to advice in the [October MHRA Drug Safety Update](#), patients taking dronedarone should have their treatment reviewed at their next routine appointment to ensure they remain eligible for treatment, according to [revised prescribing information](#), including new restrictions on use. Regular monitoring of cardiac, liver, and renal function during treatment is recommended.

#### Local recommendation

HOSPITAL ONLY. GP Advisory Committee (GPAC) approval sought for monitoring of renal and hepatic function to be undertaken in primary care.

This has been changed from the previous recommendation 'GPs may prescribe under the direction of a cardiologist'.

The local new medicine treatment protocol for dronedarone has been updated.

[Click here](#) for protocol.

#### Protocol changes - highlights:

**Section 2** - Indication restricted to 'Maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation (AF)'.

**Section 7** - additional contra-indications:

- Permanent AF with an AF duration  $\geq$  6 months (or duration unknown) and attempts to restore sinus rhythm no longer considered by the physician.
- Patients with liver and lung toxicity related to the previous use of amiodarone.
- History of, or current heart failure or left ventricular systolic dysfunction.

**Section 10** - Monitoring by primary care:

At day 7: Serum creatinine and LFTs.

Then LFTs: at month 1, 2, 3, 4, 5, 6, 9, and 12, then every 6 months thereafter.

Clinical review by secondary care 3 months after initiation then every 6 months including ECG. Annual serum creatinine, potassium and magnesium.

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## Drug Safety Updates

Please follow link - [Volume 5, Issue 6, January 2012](#)



# Prescribing Changes

## Citalopram /escitalopram - QT interval prolongation

Advice, based on a European-wide review of citalopram and escitalopram and QT interval prolongation, has been issued via [Drug Safety Update, Volume 5, Issue 5, December 2011](#) regarding **new restrictions on the maximum daily doses, contraindications, and warnings of both citalopram and escitalopram.**

The summary of product characteristics for both drugs are currently being updated to include the new recommendations as follows:

- Both drugs are now contraindicated in patients with congenital long QT syndrome or known QT interval prolongation and in combination with other medicines that prolong the QT interval
- Caution is advised in patients with pre-existing risk factors for QT interval prolongation—including patients with significant bradycardia; recent acute MI or decompensated heart failure

### **Citalopram**

- Maximum dose in adults has been reduced to 40mg daily
- In the elderly (> 65yrs) and in patients with reduced hepatic function the maximum dose is lowered to 20mg daily

### **Escitalopram ( non-formulary)**

- Maximum dose in adults remains 20mg daily
- In the elderly (>65yrs) the maximum dose has been reduced to 10mg daily
- Maximum dose in patients with reduced hepatic function remains 10mg daily

A Tayside Prescriber on 'citalopram / escitalopram - QT interval prolongation' will be issued shortly.

Medicine	Indication	Local recommendation category	Comments and useful links
Apixiban 2.5mg film-coated tablet (Eliquis®) (741/11) - <i>Full submission</i>	Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery.	<b>Not recommended</b>	<a href="#">SMC advice</a> Rivaroxaban is 1st line in NHS Tayside for this indication.
Denosumab (Xgeva®) 120 mg solution for injection (753/11) - <i>Non-submission</i>	Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumours.	<b>Not recommended</b>	<a href="#">SMC advice</a>
Dexamethasone 700 microgram intravitreal implant (Ozurdex®) (652/10) - <i>Resubmission</i>	Treatment of adult patients with macular oedema following either branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).	<b>Not recommended</b>	<a href="#">SMC advice</a>
Telaprevir, 375mg, film-coated tablets (Incivo®) (742/11) - <i>Full submission</i>	In combination with peginterferon alfa and ribavirin, for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis) who have previously been treated with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin, including relapsers, partial responders and null responders.	<b>HOSPITAL ONLY</b> (Hepatitis Clinic)  First-line protease inhibitor	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <a href="#">Drug Interaction Checker</a>  Use SPC & above website to check for drug interactions. Examples of medicines contraindicated with telaprevir - amiodarone, rifampicin, simvastatin, atorvastatin, St John's wort, phenytoin, carbamazepine.
Telaprevir, 375mg, film-coated tablets (Incivo®) (743/11) - <i>Full submission</i>	In combination with peginterferon alfa and ribavirin, for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis) who are treatment-naïve.	<b>HOSPITAL ONLY</b> (Hepatitis Clinic)  First-line protease inhibitor	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <a href="#">Drug Interaction Checker</a>

## Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Alteplase 2mg powder and solvent for solution for injection for infusion (Actilyse Cathflo®) (717/11) - <i>Abbreviated submission</i>	Thrombolytic treatment of occluded central venous access devices including those used for haemodialysis.	<b>Not recommended</b> - due to absence of clinician demand*	<a href="#">SMC advice</a>
Dronedarone 400mg film-coated tablets (Multiaq®) - <i>Full submission</i>	As of 22nd September 2011: Maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent AF. <b>Note:</b> This indication supersedes the indication reviewed by SMC.	<b>HOSPITAL ONLY</b>  <b>Cardiology Specialist List</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a> <a href="#">Local protocol</a>  GPAC approval sought for renal and hepatic monitoring by primary care.

\*Clinicians can complete a local introduction form and submit to MAG for review of local recommendation at any stage.

## Updates from previous SMC Advice continued ...

Medicine	Indication	Local recommendation category	Comments and useful links
Ticagrelor 90mg film-coated tablets (Brilique®) (699/11) - Full submission	Co-administered with aspirin, for the prevention of atherothrombotic events in adult patients with acute coronary syndromes; including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG).	<b>Not recommended</b> - due to absence of clinician demand*	<a href="#">SMC advice</a>

\*Clinicians can complete a local introduction form and submit to MAG for review of local recommendation at any stage.



## Tayside Area Formulary (TAF) Updates - Jan 2012

TAF Section	Drug(s)/topic	Changes
Specialist formulary lists and formulary development	Cardiology	<i>Dronedarone▼ restricted indication updated to reflect <a href="#">SPC</a> changes.</i>
<a href="#">2.3</a>	Dronedarone▼	<i>Dronedarone▼ entry changed to reflect <a href="#">SPC</a> changes and recent <a href="#">MHRA advice</a>. See also page 1 of this supplement.</i>

### SMC Briefing Note:

[Click here](#) for December Briefing Note

### [Forthcoming SMC Advice](#)

This bulletin is produced by the Medicines Advisory Group (MAG), which is a sub-group of the NHS Tayside Drug and Therapeutics Committee.

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