TAYSIDE PRESCRIBER

NHS Tayside

Tayside DTC Supplement No 111 – November 2011

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

Special points of interest for Primary Care

- Citalopram

SMC advice:

- Adrenaline (Jext®)
- Boceprevir (Victrelis®)
- Botulinum toxin type A (Xeomin®)
- Bromfenac (Yellox®)
- Conestat alfa (Ruconest®)
- Eribulin (Halaven®)
- Fluorouracil 0.5% / salicylic acid 10% (Actikerall®)
- Infliximab (Remicade®)
- Olmesartan/amlodipine/ hydrochlorothiazide (Sevikar HCT®)
- Quetiapine (Seroquel XL®)
- Rosuvastatin (Crestor®)
- Vardenafil (Levitra®)

Inside this issue :

Specialist list - Stroke

This specialist formulary list which was published last month has had the addition of a reference to the Perth Royal Infirmary Stroke Thrombolysis Protocol added. Click here for a link to the Stroke specialist formulary list.

Specialist lists - Progress

The E.N.T. specialist list is being finalised and is due to be published next month. Work is also ongoing to finalise the Gastroenterology and Urology specialist lists. The Endocrinology and Mental Health specialist lists are under development.

Drug Safety Updates

Please follow link - Volume 5, Issue 4, November 2011

Systemic Fusidic Acid - Interaction with Statins

Systemic fusidic acid is rarely used within NHS Tayside however it is important to be aware of the risk of rhabdomyolysis (potentially fatal) when given alongside statins. The mechanism is unknown and not necessarily specific to any particular statin; systemic fusidic acid should not be given with ANY statin. The number of case reports for this interaction are small however systemic fusidic acid is not used regularly, indicating a serious safety signal. The product information for systemic fusidic acid will be updated accordingly.
Click here for MHRA advice.

The following practical advice should be adopted to manage this interaction:

- Systemic fusidic acid and statins should NOT be given together due to the risk of potentially fatal rhabdomyolysis.
- Where systemic fusidic acid is essential, the statin should be discontinued for the duration of fusidic acid treatment and for 7 days after the last dose.
- If prolonged fusidic acid treatment is required, the need for concomitant statin therapy should be evaluated on an individual basis and only under close medical supervision. Patients should be advised to seek medical advice if muscle pain, weakness or tenderness is experienced.

Information will be available on the Antimicrobial section of the Tayside Area formulary with a link to the MHRA advice, as well as on ScriptSwitch.

Drug Safety Updates Continued

Antipsychotics During Third Trimester of Pregnancy - Newborn Effects

When antipsychotics are used during the third trimester of pregnancy, a recent Europe-wide review has concluded that there is a risk of extrapyramidal effects and/or withdrawal symptoms in the newborn. This conclusion was drawn from worldwide post-marketing surveillance and information provided from the Food and Drugs Administration (USA). The review did not quantify the magnitude of associated risk or determine the specific risks attributed to different classes or individual antipsychotics due to insufficient data. All antipsychotics will have their UK product information updated as a result of this finding. Further information can be found in Drug Safety Update: Volume 5, Issue 2, September 2011.

The following advice is given to healthcare professionals:

- If antipsychotics are taken during the third trimester, newborns should be examined for the following symptoms: agitation, hypertonia, hypotonia, tremor, somnolence, feeding problems and respiratory distress.
- Symptoms should be monitored and treated (if required); they may differ in severity and duration.
- Prospective mothers should be advised of the benefits and risks of antipsychotic use during pregnancy.
- Neonatal withdrawal symptoms may occur for at least 2 days when antipsychotics have been used up to delivery[1].
- In NHS Tayside the maternity unit would keep any mother and baby in for 3 days if the mother has been on antipsychotic medication.

1. Schaefer C et al. Chapter 2.11.6 Phenothiazines and thioxanthenes. Pg 301. Drugs during pregnancy & lactation. Treatment options and risk assessment. 2nd edition. Elsevier. Academic Press

Prescribing Changes

Adrenaline tartrate (Jext®)

Jext® is a new single-use intramuscular injection for self-administration of adrenaline for the emergency treatment of anaphylaxis. It is available in the 150microgram and 300microgram doses as with other intramuscular injections for self-administration (including Epipen®).

The advantages of Jext® include: reduced risk of inadvertent needle stick injury; and an extended shelf life of 24 months from date of manufacture. Jext® is the most cost-effective preparation based on the extended shelf life with current product costs. For these reasons Jext® is the preferred choice of intramuscular adrenaline for self-administration for new patients being prescribed adrenaline. However established patients will require to stay with their current preparation as switching to Jext® would require all patients to be retrained. Training is also essential for any new patients prescribed adrenaline for self-administration.

Jext® is bulkier and the release mechanism is different to Epipen®. For further information on Jext® and anaphylaxis, which may be useful for patients refer to http://www.jext.co.uk/. Patients can register for a service on the website to receive alerts to remind them when their device is about to expire.

Adrenaline for self-administration should always be prescribed by brand name to ensure the patient receives the device that they have been trained to use.

Citalopram - QT interval prolongation

A letter was sent from Lundbeck Limited (UK), in collaboration with the MHRA, to healthcare professionals in October this year regarding prescribing changes to citalopram after findings from a study looking at the QT interval in adults on 20mg and 60mg citalopram. No information as yet has come out through the Drug Safety Updates. Further guidance will be issued in due course. In the meantime, in line with the letter, the maximum dose of citalopram within the Tayside Area Formulary has been amended from 60mg to 40mg; and in elderly or patients with reduced hepatic function this has been amended from 40mg to 20mg.

Medicine	Indication	Local recommendation category	Comments and useful links
Adrenaline tartrate 150 and 300 microgram solution for injection in a pre-filled pen (Jext®) (687/11) - *Abbreviated submission*	Emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise induced anaphylaxis.	**Formulary**	***SMC advice*** ***SPC link (150mg)*** ***SPC link (300mg)*** ***Jext® patient information website*** ***Formulary section 3.4*** Preferred adrenaline pen for new patients. Prescribe by brand name.
Boceprevir 200mg capsule (Victrelis®) Treatment experienced patients (722/11) - *Full submission*	Treatment of chronic hepatitis C (HCV) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease who have failed previous therapy.	**Hospital Only** (Hepatitis Clinic)	***SMC advice*** ***SPC link***
Boceprevir 200mg capsule (Victrelis®) Treatment naïve patients (723/11) - *Full submission*	Treatment of chronic hepatitis C (HCV) genotype 1 infection, in combination with peginterferon and ribavirin, in adult patients with compensated liver disease who are previously untreated.	**Hospital Only** (Hepatitis Clinic)	***SMC advice*** ***SPC link***
Botulinum toxin type A, 50 and 100 LD_{50} units powder for solution for injection (Xeomin®) (731/11) - *Abbreviated submission*	Post-stroke spasticity of the upper limb presenting with flexed wrist and clenched fist in adults.	**Pending* specialist feedback**	***SMC advice***
Bromfenac (Yellox®) 0.9 mg/ml eye drops solution (740/11) - *Non submission*	Treatment of postoperative ocular inflammation following cataract extraction in adults.	**Not recommended**	***SMC advice***
Conestat alfa (Ruconest®) 2100 U powder for solution for injection (745/11) - *Non submission*	Treatment of acute angioedema attacks in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.	**Not recommended**	***SMC advice***
Eribulin 0.44mg/mL solution for injection (Halaven®) (726/11) - *Full submission*	Treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemo-therapeutic regimens for advanced disease. Prior therapy should have included an anthracycline and a taxane unless patients were not suitable for these treatments.	**Not recommended**	***SMC advice***
Fluorouracil 0.5% / salicylic acid 10% cutaneous solution (Actikerall®) (728/11) - *Full submission*	Topical treatment of slightly palpable and/ or moderately thick hyperkeratotic actinic keratosis (grade I/II) in immunocompetent adult patients.	**Formulary**	***SMC advice*** ***SPC link*** ***Formulary section 13.8***
Infliximab (Remicade®) 100 mg powder for concentrate for solution for infusion (739/11) - *Non submission*	Treatment of moderately active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.	**Not recommended**	***SMC advice***
Olmesartan medoxomil/amlodipine besilate/hydrochlorothiazide 20mg/5mg/12.5mg, 40mg/5mg/12.5mg, 40mg/10mg/12.5mg, 40mg/5mg/25mg, 40mg/10mg/25 mg film-coated tablets (Sevikar HCT®) (706/11) - *Abbreviated submission*	As substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of olmesartan medoxomil, amlodipine, and hydrochlorothiazide taken as a dual component (olmesartan medoxomil and amlodipine or olmesartan medoxomil and hydrochlorothiazide) and a single formulation (hydrochlorothiazide or amlodipine).	**Not recommended**	***SMC advice***
Quetiapine (Seroquel XL®) 50 mg, 150 mg, 200 mg, 300mg 400 mg prolonged-release tablets (744/11) - *Non submission*	Add-on treatment of major depressive episodes in patients with Major Depressive Disorder (MDD) who have had sub-optimal response to antidepressant monotherapy.	**Not recommended**	***SMC advice***

SMC Advice issued in October 2011 - continued….

Medicine	Indication	Local recommendation category	Comments and useful links
Rosuvastatin, 5mg, 10mg, 20mg, film-coated tablets (Crestor®) (725/11) *- Full submission*	Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event as an adjunct to correction of other risk factors.	**Not recommended**	*SMC advice*
Vardenafil 10mg orodispersible tablet (Levitra®) (727/11) *- Full submission*	Treatment of erectile dysfunction (ED) in adult men. ED is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for vardenafil to be effective, sexual stimulation is required.	**Not recommended -** due to absence of clinician demand.	*SMC advice*

* 'pending' means that no local recommendation to support use is in place at the current time

Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Retigabine 50mg, 100mg, 200mg, 300mg and 400mg film-coated tablets (Trobalt®) (712/11) *- Full submission*	Adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy.	GPs may prescribe under the direction of the Neurology Clinic. Restricted to patients with refractory epilepsy.	*SMC advice* *SPC link*

Tayside Area Formulary (TAF) Updates - Nov 2011

TAF Section	Drug(s)/topic	Changes
Specialist formulary lists and formulary development	**Renal**	***Brand of Hepatitis B vaccine changed from Fendrix® to HBvaxPRO®.***
	Stroke	***Addition of reference to PRI Stroke Thrombolysis Protocol.***
2.10	**Alteplase**	***Addition of reference to PRI Stroke Thrombolysis Protocol.***
3.4	**Adrenaline**	***Jext®* (adrenaline as tartrate) added to formulary as the preferred choice of intramuscular adrenaline injection for self-administration for new patients being prescribed adrenaline. See page 2 of this supplement for further details.***
4.3	**Citalopram**	***Maximum dose reduced from 60mg to 40mg; in elderly and hepatic impairment dose reduced from 40mg to 20mg.***
13.8	**Photodamage**	***Addition of treatments for actinic keratoses to formulary: Diclofenac 3% gel (Solaraze®); fluorouracil 5% cream (Efudix®); imiquimod 5% cream (Aldara®)* (restricted use). Link to local protocol for imiquimod 5% cream for actinic keratoses added. Addition of Fluorouracil 0.5% / salicylic acid 10% Cutaneous Solution (Actikerall®)* to formulary as a spot treatment for mild to moderate actinic keratoses in immunocompetent adults if cryotherapy is not available.***

*** SMC accepted medicine**

SMC Briefing Note:

CLICK HERE for October 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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