



Tayside DTC Supplement No 121 – November 2012

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

Special points of interest for Primary Care

- PPIs - fracture risk & hypomagnesaemia
- Oseltamivir suspension
- BNF e-newsletter

SMC advice:

- Bevacizumab (Avastin®)
- Caffeine citrate (Peyona®)
- Fluticasone/formoterol (Flutiform®)
- Ivabradine (Procoralan®)
- Pasireotide (Signifor®)
- Strontium ranelate (Protelos®)
- Tocoferolsol (Vedrop®)
- Velaglucerase (VPRIV®)
- Zonisamide (Zonegran®)

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Drug Safety Updates

Please follow links - [Volume 6, Issue 3, October 2012](#)

[Volume 6, Issue 4, November 2012](#)

Risk of fractures & hypomagnesaemia with proton pump inhibitors

Proton pump inhibitors (PPIs) can increase the risk of fractures, particularly when used at high doses for over a year in the elderly. Reports of hypomagnesaemia have also been reported with prolonged doses of PPIs. For further information see [Drug Safety Update Volume 5, Issue 9, April 2012](#) and [BNF section 1.3.5 Proton Pump Inhibitors](#).

For local guidance on reducing inappropriate PPI use in older people [CLICK HERE](#).

Dipeptidylpeptidase-4 inhibitors ('gliptins'): risk of acute pancreatitis

The formulary currently has a warning of pancreatitis with saxagliptin, and to discontinue in suspected cases of persistent and severe abdominal pain. The MHRA has just issued the warning as a class effect across all DPP-4 inhibitors in the Drug Safety Update [MHRA Sep 2012](#). It is now included in the SPCs for all DPP-4 inhibitors as a possible adverse reaction. Although the precise frequency is unknown, a few cases have been reported in clinical trials. This was found with post-marketing experience for most of the compounds, except for linagliptin where the increased number of cases compared with placebo was detected in clinical development. Diabetics generally have a higher risk of pancreatitis compared to non-diabetics.



Prescribing Changes

Change to Oseltamivir (Tamiflu®) Oral Suspension Concentration

Oseltamivir (Tamiflu®) is licensed in patients aged 1 year and above for the treatment of influenza when the virus is circulating in the community and also to prevent influenza in individuals who have come into contact with a diagnosed case of influenza if it is circulating in the community. From October 2012 the concentration of the available oseltamivir oral suspension will change from 12mg/mL to 6mg/mL to allow for more accurate dosing. Along with the change in concentration, a new dosing dispenser will be introduced which will be calibrated in millilitres. All healthcare professionals should state the required dose in milligrams and for further information on this refer to the updated summary of product characteristics (SPC) which can be found [HERE](#). When prescribing oseltamivir liquid, all healthcare professionals must ensure that the patient/carer are aware of the changes from the product they may have had previously and of the updated patient information leaflet with guidance on administration.

For further information please refer to [MHRA Drug Safety Update Volume 6, Issue 2, September 2012](#).



BNF e-newsletter

The BNF and BNF for children (BNFC) e-newsletter is a free alert service for healthcare professionals that is produced when a new edition of either publication is launched. From October 2012 it will be produced monthly in tandem with the launch of monthly online updates to the BNF and BNFC. It alerts healthcare professionals to details of significant changes in the clinical content of these publications and to the way that this information is delivered. Newsletters also review clinical case studies and provide tips on using these publications effectively. [Click here](#) to sign up for e-newsletters. Past copies are available from the [e-newsletter archive](#), accessible from the home page of the [BNF](#).

Previous case studies include:

- Community acquired pneumonia in under 2 years
- Management of hypertension
- Antipsychotics - extrapyramidal and metabolic side effects profile
- Treatment & prevention of meningitis
- Hormonal contraception

SMC Advice issued in October 2012

SMC website: www.scottishmedicines.org.uk

Medicine	Indication	Local recommendation category	Comments and useful links
Bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®) (806/12) - Full submission	In combination with carboplatin and paclitaxel is indicated for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics [FIGO] stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer.	Not recommended	SMC advice
Caffeine citrate (Peyona®) 20mg/ml solution for infusion and oral solution (814/12) - Non-submission	Treatment of primary apnoea of premature newborns.	Not recommended	SMC advice
Fluticasone propionate and formoterol fumarate MDI (Flutiform®) (736/11) - Abbreviated submission	In the regular treatment of asthma where the use of a combination product is appropriate: – for patients not adequately controlled on ICS and ‘as required’ inhaled short-acting Beta ₂ agonist or – for patients already adequately controlled on both ICS and a LABA.	Pending* Respiratory MCN decision	SMC advice
Ivabradine 5 and 7.5mg film-coated tablets (Procoralan®) (805/12) - Full submission	Chronic heart failure New York Heart Association (NYHA) II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥75 beats per minute (bpm), in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contra-indicated or not tolerated.	GPs may prescribe under the direction of Cardiology/Heart Failure Clinic or the Heart Failure Nurses Liaison Services. Cardiology Specialist List Restricted to patients whose resting HR remains ≥75 beats per minute despite optimal standard therapy.	SMC advice SPC link Note that ivabridine is ineffective in atrial fibrillation
Pasireotide (Signifor®) 0.3mg, 0.6 mg and 0.9 mg solution for injection (815/12) - Non-submission	Treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed.	Not recommended	SMC advice
Strontium ranelate (Protelos®) 2g granules for oral suspension (816/12) - Non-submission	Treatment of osteoporosis in men at increased risk of fracture.	Not recommended	SMC advice

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

Medicine	Indication	Local recommendation category	Comments and useful links
Tocofersolan, 50mg/mL (corresponding to 74.5 IU tocopherol) oral solution (Vedrop®) (696/11) - Re-submission	Vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis, from birth (in term newborns) to 16 or 18 years of age, depending on the region.	Not recommended	SMC advice
Velaglucerase alfa 400 units powder for solution for infusion (VPRIV®) (681/11) - Full submission	Long-term enzyme replacement therapy in patients with type I Gaucher disease.	Restricted to supply by specialists working in a national (UK) lysosomal storage disease centre. Supplied via Patient Access Scheme (PAS).	SMC advice SPC link
Zonisamide (Zonegran®) 25, 50, 100mg Hard Capsules (817/12) - Non-submission	Monotherapy for the treatment of partial seizures (with or without secondary generalization) in adults with newly diagnosed epilepsy.	Not recommended	SMC advice

Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Colecalciferol 800 international units (equivalent to 20 micrograms vitamin D ₃) capsules (Fultium-D ₃ ®) (801/12) - Full submission	In adults, the elderly and adolescents for the prevention and treatment of vitamin D deficiency and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.	<u>Vitamin D deficiency</u> Formulary - restricted to treatment of vitamin D deficiency. <u>Osteoporosis</u> Formulary - restricted to patients in whom a combined vitamin D and calcium supplement is unsuitable.	SMC advice SPC NHS Tayside Guidelines for Investigation and Treatment of Vitamin D Deficiency Vitamin D for maintenance therapy should normally be purchased OTC. Combined vitamin D and calcium supplementation is recommended first-line as an adjunct to osteoporosis therapy. TAF first-choice is Calceos®.
Fingolimod (as hydrochloride), 0.5mg hard capsules (Gilenya®) (763/12) - Re-submission	As single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups: - Patients with high disease activity despite treatment with a beta-interferon; OR - Patients with rapidly evolving severe RRMS.	Non-formulary - pending protocol SMC restriction - patients with high disease activity despite treatment with beta-interferon	SMC advice SPC link

'Local processes exist to allow consideration of prescribing outwith SMC advice or outwith NHS Tayside formulary. Details are available in the [NHS Tayside Policy on the Prescribing of Medicines that are Non-formulary \(including Individual Patient Treatment Requests\)](#)'

Tayside Area Formulary (TAF) Updates - Nov 2012

TAF Section	Drug(s)/topic	Changes
1.3 Ulcer Healing Drugs	Proton Pump Inhibitors	Information added regarding risk of fractures & hypomagnesaemia with PPIs and link to Drug Safety Update Volume 5, Issue 9, April 2012 and BNF section 1.3.5 Proton Pump Inhibitors added.
4.3 & 4.7.3	Antidepressant combination advice - depression & neuropathic pain	Paragraph added regarding review of currently prescribed antidepressants before initiating any other antidepressant for depression or neuropathic pain. Information on dose titration added for fluoxetine.
4 CNS Guidelines – Psychiatric guidance notes	Using Antidepressants in Primary Care	Sentence added regarding review of currently prescribed antidepressants before initiating any other antidepressant for depression. Seek specialist advice added if concern regarding switching antidepressants. Link to MIMS table on Switching Antidepressants added.
6.6	Drugs affecting bone metabolism - Denosumab	The denosumab protocol has been updated - DEXA scan may be performed at base-line and between 48 and 60 months (previously at 24 and 36 months). Link updated in TAF and Medicines for the Elderly and Endocrine specialist lists.
9.6 Vitamins	Vitamin B Group	Dose of Pabrinex® I/V High Potency Injection for treatment of Wernicke's encephalopathy changed to 2 to 3 pairs of ampoules three times a day for 2 days then as before. Dose for prophylaxis is one pair of ampoules three times a day for 2 days then as before.

* = SMC accepted medicine

Wound Management Formulary (WMF) Updates - Oct 2012

Section	Topic	Changes
3	Care of the Surrounding Skin	Section reviewed and updated. Printer friendly version added.
7	Diabetic Foot Ulcers	Section reviewed and updated. First and second line dressing choices now stated, links to diabetic handbook and printer friendly version added.
8	Minor Wounds	Section removed.
11	IV Sites	Section removed.
<p>Please direct any queries in relation to the Wound Management Formulary to: Suzanne Waterston, Advanced Clinical Pharmacist: Dermatology, email swaterston@nhs.net</p>		

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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Local implementation of SMC recommendations is taken forward by the Tayside Medicines Governance Unit. This bulletin is based on evidence available to the Tayside Medicines Governance Unit at time of publication and is covered by the Disclaimer and Terms & Conditions of use.

[CLICK HERE](#) for access to the Medicines Governance section of the Pharmacy Staffnet site.