



Tayside DTC Supplement No 100 – October/November 2010

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

Special points of interest for Primary Care

- Change to choice of oral contraceptives
- Levothyroxine oral solution - change in formulation
- Oral bisphosphonates and oesophageal cancer

SMC advice:

- Ethinylestradiol / desogestrel (Gedarel®)
- Ethinylestradiol / gestodene (Millinette®)
- Ethinylestradiol / levonorgestrel (Rigevidon®)
- Ethinylestradiol / levonorgestrel (TriRegol®)
- Esomeprazole gastro-resistant granules for oral solution
- Glucosamine sulphate
- Roflumilast tablets
- Pregabalin update
- Tadalafil update



Guidelines and Protocols

Dermatology Biologics Guidelines

This local guideline has been developed using British Association of Dermatologists (BAD) guidance, National Institute for Clinical Excellence (NICE) guidance and Scottish Medicines Consortium (SMC) advice.

If a person has both psoriasis and psoriatic arthritis their treatment should be managed by collaboration between a rheumatologist and a dermatologist.

There are currently three approved classes of biologic agents for psoriasis. Two classes target TNF:

- anti-TNF monoclonal antibodies (adalimumab and infliximab),
- soluble TNF receptors (etanercept) and ustekinumab which is a fully human IgG1k monoclonal antibody that acts as an IL inhibitor.

It is recommended that the use of these drugs for psoriasis should be initiated and supervised only by specialist physicians experienced in the diagnosis and treatment of psoriasis.

For updates on the local recommendations for ustekinumab and infliximab please go to page 5 and 6 of this Supplement.

[Click here](#) to access a full copy of the Guidelines and associated references.

Dronedarone – changes to the local protocol

Section 10 of this protocol has been modified in order to clarify the monitoring arrangements.

As noted in the [Summary of Product Characteristics \(SPC\) for dronedarone \(Multaq®\)](#), serum creatinine values should be measured 7 days after initiation of dronedarone.

An expected increase in serum creatinine levels due to the known effect of dronedarone on renal tubular excretion does not indicate impaired renal function. However the increased value should be used as the patient's new baseline. This measurement of serum creatinine is to be undertaken by primary care.

All regular monitoring for patients taking dronedarone is undertaken by secondary care at out-patient clinic visits. GPs should be aware that signs or symptoms of new or worsening of heart failure requires immediate secondary care specialist referral.

For further information please [click here](#).

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Drug Safety Updates

Oral bisphosphonates and oesophageal cancer

A recent article in the BMJ suggests a small increased risk of oesophageal cancer in people taking oral bisphosphonates.

This risk was reviewed by the Commission on Human Medicines (CHM). There were strengths and limitations to the study. The CHM concluded that there is insufficient evidence to suggest a definite association between oral bisphosphonate use and oesophageal cancer.

The benefits of bisphosphonate treatment are still considered to outweigh the risks.

Reference:

- I. Green et al. Oral bisphosphonates and risk of cancer of oesophagus, stomach, and colorectum: case-control analysis within a UK primary care cohort. BMJ 2010;341:c4444 doi:10.1136/bmj.c4444

For further information:

Please refer to the [MHRA Questions & Answers on the study by Green et al.](#) and the [Drug Safety Update vol 4; issue 4, November 2010](#)

Levothyroxine oral solution 25 micrograms / 5mL, 50 micrograms / 5mL, 100 micrograms / 5 mL - change in formulation

Kappin Ltd, the manufacturers of the Evotrox® and Almus® brand of levothyroxine oral solution have changed the formulation of all three strengths. This has resulted in a 10 % increase in potency of all strengths. The new packs will be marked with 'New Formulation' on the carton.

Levothyroxine oral solution is not widely used in Tayside as most patients can take levothyroxine oral tablets. This change in potency is unlikely to have significant clinical effects in the majority of patients.

However, there may be a small group for which it may be appropriate to ensure that TSH levels are monitored within 3 months of receiving this new formulation. This may include elderly patients and patients with pre-existing cardiac disease that are being maintained on relatively high doses or are already at the lower end of the range for TSH. For example, this equates to a 25 microgram dose increase in patients who are currently on 250 micrograms daily.

Key points :

- The change in potency is unlikely to have significant clinical effects in the majority of patients.
- You may need to monitor TSH levels in elderly patients or people with pre-existing cardiac disease within 3 months of receiving this new formulation.



Prescribing Changes

Choice of Combined Oral Contraceptives



Please see page 3 for the local formulary recommendations for these preparations

The Tayside Area Formulary (TAF) choices of [combined oral contraceptives](#) have changed. Several new brands of combined oral contraceptives have been approved by SMC and these have replaced several equivalent products within the formulary as they provide potential cost savings.

The ScriptSwitch general practice prescribing program will be updated in line with formulary changes so that these alternative equivalent products are suggested for prescribing. It is however recommended that **prescribers should not change patient's prescriptions for contraceptives to the newer products without appropriate communication with patients.** Patients should be reassured that the newer products contain the same ingredients at the same dose, however packaging and colours of pills differ from previous brands.

Healthcare professionals and patients may find the website for the new products useful:
<http://www.knowyourcontraceptives.co.uk/>.

This website details product information including manufacturer's SPCs, pictures of packaging of the new contraceptives and other support materials. There is also a facility to download a free mobile phone application to remind women to take their oral contraceptive each day and after the 7 day break, and to remind of the need for repeat prescription.

Medicine	Indication	Local recommendation category	Comments and useful links
Amifampridine (Firdapse®) (660/10) - Non submission	Treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) in adults	Not recommended	SMC advice
Canakinumab (Ilaris®) 150 mg/ml, powder for solution for injection intended (658/10) - Non submission	Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 4 years and older with body weight above 15 kg	Not recommended	SMC advice
Certolizumab pegol 200mg/ml solution for injection (prefilled syringe) (Cimzia®) (590/09) - Resubmission	- In combination with methotrexate for the treatment of moderate to severe active rheumatoid arthritis in adult patients when the response to disease modifying anti-rheumatic drugs, including methotrexate, has been inadequate - Monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate	Pending specialist feedback To be supplied via a Patient Access Scheme	SMC advice
Docetaxel (Taxotere®) 20 mg/1 mL and 80 mg/4 mL and 160 mg/8 mL concentrate for solution for infusion (659/10) - Non submission	Adjuvant treatment of patients with operable node-negative breast cancer	Not recommended	SMC advice
Eculizumab, 300mg concentrate for solution for infusion (Soliris®) (436/07) - Full submission	Treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH)	Not recommended	SMC advice
Eslicarbazepine acetate 800mg tablet (Zebinix®) (592/09) - Resubmission	As adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation	Pending specialist feedback To be supplied via a Patient Access Scheme	SMC advice
Ethinylestradiol 20microgram/desogestrel 150microgram (Gedarel® 20/150 microgram) film-coated tablets (643/10) - Abbreviated submission	Oral contraception	Non formulary (replaces Mercilon®)	SMC advice SPC link
Ethinylestradiol 30microgram/desogestrel 150microgram (Gedarel® 30/150 microgram) film-coated tablets (643/10) - Abbreviated submission	Oral contraception	Formulary - 2nd line choice (replaces Marvelon®)	SMC advice SPC link Tayside Area Formulary
Ethinylestradiol 20microgram/gestodene 75microgram (Millinette® 20/75 microgram) film-coated tablets (644/10) - Abbreviated submission	Oral contraception	Formulary - 2nd line choice (replaces Femodette®)	SMC advice SPC link Tayside Area Formulary
Ethinylestradiol 30microgram/gestodene 75microgram (Millinette® 30/75 microgram) film-coated tablets (644/10) - Abbreviated submission	Oral contraception	Formulary - 2nd line choice (replaces Femodene®)	SMC advice SPC link Tayside Area Formulary
Ethinylestradiol 30microgram and levonorgestrel 150microgram (Rigevidon® 30/150 microgram) film-coated tablets (646/10) - Abbreviated submission	Oral contraception	Formulary - 1st line choice (replaces Microgynon 30® / Ovranette®)	SMC advice SPC link Tayside Area Formulary
Ethinylestradiol 30/40microgram/levonorgestrel 50/ 75/125microgram (TriRegol®) film-coated tablets (645/10) - Abbreviated submission	Oral contraception	Non formulary (replaces Logynon®)	SMC advice SPC link
Glucosamine sulphate 1,500mg powder for oral solution (Glusartel®) (647/10) - Full submission	Relief of symptoms in mild to moderate osteoarthritis (OA) of the knee	Not recommended	SMC advice

SMC Advice issued in October/November 2010 - continued.....

Medicine	Indication	Local recommendation category	Comments and useful links
Lanthanum carbonate 500mg, 750mg, 1,000mg chewable tablets (Fosrenol®) (640/10) - Full submission	As a phosphate binding agent for use in the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphate levels $\geq 1.78\text{mmol/L}$ in whom a low phosphate diet alone is insufficient to control serum phosphate levels	Not recommended	SMC advice
Oxycodone hydrochloride 50mg/ml solution for injection or infusion (OxyNorm®) (648/10) - Full submission	Treatment of moderate to severe pain in patients with cancer	Pending risk management assessment	SMC advice
Pemetrexed 100mg, 500mg powder for concentrate for solution for infusion (Alimta®) (642/10) - Full submission	Monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. First-line treatment should be a platinum doublet with gemcitabine, paclitaxel or docetaxel	Not recommended	SMC advice
Roflumilast 500microgram tablets (Daxas®) (635/10) - Full submission	Maintenance treatment of severe chronic obstructive pulmonary disease (COPD) (forced expiratory volume in 1 second [FEV ₁] post-bronchodilator <50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment	Not recommended	SMC advice
Sevelamer carbonate, 800mg film-coated tablets (Renvela®) (641/10) - Full submission	Control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis	Not recommended	SMC advice
Trabectedin, 0.25 and 1mg powder for concentrate for solution for infusion (Yondelis®)(452/08) - Re-submission	Treatment of patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents	Not recommended	SMC advice

Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Bivalirudin 250mg powder for concentrate for solution for injection or infusion (Angiox [®]) (516/08) - Full submission	Treatment of adult patients with acute coronary syndrome (unstable angina/non-ST segment elevation MI) planned for urgent or early intervention. Bivalirudin should be administered with aspirin and clopidogrel	Not routinely recommended in Tayside	SMC advice
Bivalirudin 250mg powder for concentrate for solution for injection or infusion (Angiox [®]) (638/10) - Full submission	As an anticoagulant in adult patients undergoing percutaneous coronary intervention (PCI), including patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary PCI. Bivalirudin should be administered with aspirin and clopidogrel	Not routinely recommended in Tayside	SMC advice
Esomeprazole 10mg gastro-resistant granules for oral solution, sachet (Nexium [®]) (639/10) - Abbreviated submission	Primarily indicated for treatment of gastro-oesophageal reflux disease in children 1 to 11 years old. Gastro-oesophageal reflux disease (GORD) - Treatment of endoscopically proven erosive reflux oesophagitis - Symptomatic treatment of gastro-oesophageal reflux disease	Non formulary May be prescribed by GPs under the direction of the Paediatric GI clinic Restricted to patients in whom licensed doses of a generic PPI have been ineffective	SMC advice SPC link BNF for children
Infliximab 100mg powder for intravenous infusion (Remicade [®]) - Full submission	Treatment of severe plaque psoriasis in adults who have failed to respond to, or who have a contraindication to, or are intolerant of other systemic therapy including ciclosporin, methotrexate or psoralen ultraviolet A (PUVA)	HOSPITAL ONLY Restricted to patients who require rapid disease control	SMC advice SPC link Guidelines- Biological Treatment of Severe Psoriasis
Ivabradine (Procoralan [®]) - Resubmission	Chronic stable angina	Formulary—restricted use Restricted to angina patients intolerant of beta blockers and rate-limiting calcium channel blockers who remain symptomatic despite nitrates/nicorandil	SMC advice SPC link Tayside Area Formulary
Pregabalin 25, 50, 75, 100, 150, 200 and 300mg capsules (Lyrica [®]) — 2 nd resubmission	Treatment of peripheral neuropathic pain in patients who have not achieved adequate pain relief from, or did not tolerate, first and second line drug treatments	Formulary—restricted use	SMC advice SPC link Tayside Prescriber on Management of Neuropathic Pain
Tadalafil 2.5mg and 5mg film-coated tablets (Cialis [®]) - Abbreviated submission	For once daily administration in patients with erectile dysfunction responding to an on-demand regimen of tadalafil who anticipate frequent use (at least twice weekly)	HOSPITAL ONLY To be initiated and prescribed by the Erectile Dysfunction Clinic only	SMC advice SPC link Use is subject to the same NHS prescribing restrictions as other treatments for erectile dysfunction in terms of NHS GMS Scotland regulations
Tocilizumab (RoActemra [®]) 200mg/mL concentrate for solution for injection Full submission	Moderate to severe active rheumatoid arthritis in adult patients	HOSPITAL ONLY Restricted for use in combination therapy within NHS Scotland	SMC advice SPC link
Ustekinumab 45mg solution for injection (Stelara [®]) - Full submission	Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate and psoralen and UVA treatment (PUVA)	HOSPITAL ONLY 2nd line Biologic for the treatment of severe psoriasis Supplied via a Patient Access Scheme (PAS) for those people weighing over 100kg	SMC advice SPC link Guidelines- Biological Treatment of Severe Psoriasis



Tayside Area Formulary (TAF) Updates - Oct/Nov

TAF Section	Drug(s)/topic	Changes
2.5	Angiotensin –II receptor antagonists	<i>Losartan replaces candesartan as 1st choice angiotensin-II receptor antagonist for hypertension (in ACE-inhibitor intolerant patients). Candesartan remains 1st choice angiotensin-II receptor antagonist for heart failure (in ACE-inhibitor intolerant patients).</i>
2.6	Other antianginal drugs	<i>Addition of ivabradine to formulary (restricted use). Indication remains as before however previous local recommendation non-formulary.</i>
3.0	Respiratory System and Guidelines	<i>See Tayside Prescriber Issue 119 - Respiratory MCN Formulary Update for a summary of the changes.</i>
4.7	Drugs for neuropathic pain	<i>Minor change to wording on pregabalin to ensure consistency with Management of Neuropathic Pain guidance.</i>
Section 4 CNS Guidelines - Pain Guidance Notes	Management of Neuropathic Pain	<i>Duration of treatment with gabapentin after which alternative treatment should be considered if no improvement changed from 6 weeks to 8 weeks. Minor changes to wording throughout to improve clarity.</i>
7.3	Combined oral contraceptives	<i>Rigevidon® now Formulary - 1st line choice (replaces Microgynon 30® / Ovranette®). Gedarel® 30/150 now Formulary - 2nd line choice (replaces Marvelon®). Millinette® 30/75 now Formulary - 2nd line choice (replaces Femodene®). Millinette® 20/75 now Formulary - 2nd line choice (replaces Femodette®).</i>
9.4	Oral nutrition	<i>Link to the NHS Tayside Nutrition Standards website inserted.</i>
10.3	Drugs used for the relief of soft tissue inflammation	<i>Statement on use of topical NSAIDs updated to reflect advice within Clinical Knowledge Summary-osteoarthritis and NICE Clinical Guideline on Osteoarthritis. Piroxicam 0.5% gel highlighted as current product with lowest acquisition cost.</i>

And Finally.....

MAG will meet monthly in the New Year

It has been decided to re-instate the monthly meetings of the Medicines Advisory Group (MAG) to accommodate an ever increasing workload and the approval process for the Specialist Formulary Lists. A proposal was submitted to and approved by the Area Drug and Therapeutics Committee on the 18th October 2010. The first meeting of 2011 will be held on the **18th January**.

For a full list of dates please [click here](#)

SMC Briefing Note:

Click here for [October](#) and November Briefing Notes

[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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