

# TAYSIDE PRESCRIBER



## Tayside DTC Supplement No 96 – April/May 2010

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



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## Generic clopidogrel prescribing and licensed indications

- NHS Tayside recommends the prescribing of generic clopidogrel for all indications where branded clopidogrel has previously been used
- Generic clopidogrel is bioequivalent to the branded version
- Some marketing restrictions apply to the generic agents and as a result, generic manufacturers cannot include the acute coronary syndrome as a licensed indication
- Generic clopidogrel is considerably cheaper than the branded version
- Prescribers in primary care and in hospital should continue to write prescriptions for generic clopidogrel.

## Simvastatin increased risk of myopathy at high dose (80mg)

There is an increased risk of myopathy associated with high dose (80 mg) simvastatin. The 80mg dose should be considered only in patients with severe hypercholesterolaemia and high risk of cardiovascular complications who have not achieved their treatment goals on lower doses, when the benefits are expected to outweigh the potential risks. Please refer to the [MHRA Drug Safety Update May 2010](#) for further information.

### Recommendations:

- Prescribers treating patients who are taking simvastatin 80 mg or who are being considered for an up-titration to that dose may need to review their treatment during their next visit, to take into account the new evidence
- Patients who are currently taking simvastatin 80 mg should not stop taking their medicine. However, they should be advised to contact their doctor immediately if they experience unexplained muscle pain, tenderness, or weakness.

The 80mg dose of simvastatin is **not** included within the Tayside Area Prescribing Guide (TAPG). This was removed in May 2009 as this dose should only be considered in particular patients. Simvastatin 40mg remains the first choice statin within the TAPG.

## Clopidogrel and Proton Pump Inhibitors (PPIs) – Update and amended advice

**(This supersedes the advice given in DTC supplements No. 89, 90 & 93)**

PPIs other than omeprazole and esomeprazole appear not to interact with clopidogrel, although the available data is not totally consistent. Since it is not possible to completely exclude a possible interaction with these PPIs and clopidogrel, the potential risk of a slight reduction in efficacy of clopidogrel should be weighed against the gastrointestinal benefit of the PPI.

Refer to the [MHRA Drug Safety Update April 2010](#) for further information.

### Updated Recommendations:

- Patients should not routinely be prescribed a PPI whilst on dual anti-platelet therapy
- Prescribe PPIs strictly in line with their licensed indications
- Check that patients on clopidogrel are not buying over the counter omeprazole
- In patients on dual antiplatelet therapy and a history of gastric ulceration or dyspepsia, ranitidine 150 to 300mg twice daily should be prescribed
- If a PPI is required avoid omeprazole or esomeprazole unless considered essential.
- In complicated cases, for example, Barrett's oesophagus, advice should be sought between the cardiologist and gastroenterologist on an individual patient basis
- Discourage concomitant use of other known CYP2C19 – inhibiting medicines. These include fluvoxamine, fluoxetine, moclobemide, voriconazole, fluconazole, ticlopidine, ciprofloxacin, cimetidine, carbamazepine, oxcarbazepine and chloramphenicol.

## New edition of the Tayside Area Prescribing Guide (TAPG) Pocket Guide

Version 4 of the TAPG pocket guide is now available.

The pocket guide is designed to provide a handy compact reference to medicines recommended within the TAPG. The most up to date version of the TAPG will continue to be maintained in electronic form at: <http://www.nhstaysideadtc.scot.nhs.uk/approved/formular/formular.htm> or via the homepage of NHS Tayside Staffnet.

The pocket guide has been distributed widely to prescribers, pharmacists, wards and clinical areas throughout NHS Tayside. If you have not received a copy and wish to be included on the distribution list please email: [moragbrown@nhs.net](mailto:moragbrown@nhs.net).

## Delayed Antibiotic Prescriptions in Primary Care

It is well known that antibiotic resistance rates are strongly related to antibiotic use in primary care. Approximately 60% of all antibiotic prescribing in general practice is for respiratory tract infections. Overall antibiotic prescribing for some types of respiratory tract infection can be significantly reduced whilst maintaining patient satisfaction and good clinical outcomes by offering a delayed antibiotic prescription. Each practice in NHS Tayside has been issued with delayed antibiotic prescribing information and patient information leaflets in an attempt to encourage the adoption of this method of prescribing.

Further information on delayed antibiotic prescribing for respiratory tract infections can be found on <http://guidance.nice.org.uk/CG69/Guidance/pdf/English>

## SMC Advice issued in April/May 2010

SMC website: [www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk)

Medicine	Indication	Local recommendation category	Comments and useful links
Abatacept (Orencia®) - <i>Non submission</i>	Treatment of juvenile idiopathic arthritis	<b>Not recommended</b>	<a href="#">SMC advice</a>
Azacitidine 100mg powder for suspension for injection (Vidaza®) - <i>Full submission</i>	Treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (SCT) with intermediate-2 and high-risk myelodysplastic syndrome (MDS), chronic myelomonocytic leukaemia (CMML) or acute myeloid leukaemia (AML)	<b>Not recommended</b>	<a href="#">SMC advice</a>
Everolimus 5 and 10mg tablets (Afinitor®) - <i>Full submission</i>	Treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy	<b>Not recommended</b>	<a href="#">SMC advice</a>
Extended release nicotinic acid/laropiprant 1000mg/20mg modified release tablets (Tredaptive®) - <i>Full Submission</i>	Treatment of dyslipidaemia, particularly in patients with combined mixed dyslipidaemia (characterised by elevated levels of LDL-cholesterol and triglycerides and low HDL-cholesterol) and in patients with primary hypercholesterolaemia (heterozygous familial and non familial) as monotherapy in patients in whom HMG-CoA reductase inhibitors are considered inappropriate or not tolerated	<b>Non formulary</b> GPs may prescribe under the direction of the Cardiovascular Risk Clinic  Restricted to use as monotherapy for the treatment of dyslipidaemia in patients with combined mixed dyslipidaemia and in whom: <ul style="list-style-type: none"> <li>statins are considered inappropriate or not tolerated</li> <li>both statins and fibrates are considered inappropriate or not tolerated.</li> </ul>	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Gefitinib 250mg film-coated tablets (Iressa®) - <i>Full submission</i>	For the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor tyrosine kinase (EGFR-TK)	<b>Not recommended</b>	<a href="#">SMC advice</a>
Lenalidomide, 5mg, 10mg, 15mg and 25mg capsules (Revlimid®) - <i>Resubmission</i>	In combination with dexamethasone, for the treatment of multiple myeloma patients who have received at least one prior therapy	<b>HOSPITAL ONLY</b> Recommended within specialist treatment pathway  Restricted to use in patients who have received at least two prior lines of therapy	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Metformin 500mg and 1000mg powder for oral solution (Glucophage®) - <i>Abbreviated submission</i>	Treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control	<b>Non Formulary</b>  Restricted to patients unable to swallow the solid dosage form	<a href="#">SMC advice</a> <a href="#">SPC link</a> <i>Be aware of patient's nutritional intake if unable to swallow</i>

## SMC Advice issued in April/May 2010 - continued

SMC website: [www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk)

Medicine	Indication	Local recommendation category	Comments and useful links
Omalizumab 150mg powder and solvent for solution for injection (Xolair®) - <i>Abbreviated submission</i>	Add-on therapy to improve asthma control in children (6 to <12 years of age) with severe persistent allergic asthma who have a positive skin test or <i>in vitro</i> reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist	Pending specialist feedback	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Paclitaxel albumin powder for suspension for infusion (contains 100mg paclitaxel as paclitaxel albumin) (Abraxane®) - <i>Full submission</i>	Treatment of metastatic breast cancer in patients who have failed first-line treatment for metastatic disease and for whom standard anthracycline containing therapy is not indicated	Not recommended	<a href="#">SMC advice</a>
Raltegravir 400mg film-coated tablet (Isentress®) - <i>Full submission</i>	In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients	<b>HOSPITAL ONLY</b> (HIV clinic)  Restricted use for patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PI s) when these options are compromised due to drug-drug interactions	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Sitagliptin 50mg and metformin hydrochloride 1000mg tablets (Janumet® 50/1000) - <i>Abbreviated submission</i>	As an adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes mellitus inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of sitagliptin and metformin	<b>Non Formulary</b>  Restricted to use in patients for whom a combination of sitagliptin and metformin is an appropriate choice of therapy and only when the addition of sulphonylureas to metformin monotherapy is not appropriate. Sitagliptin represents an alternative to other agents such as thiazolidinediones	<a href="#">SMC advice</a>
Tacrolimus 0.03% ointment (Protopic®) - <i>Full submission</i>	Maintenance treatment of moderate to severe atopic dermatitis in children (aged 2 to 15 years) for the prevention of flares and the prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected)	Pending specialist feedback	<a href="#">SMC advice</a> <a href="#">SPC link</a>

## SMC Advice issued in April/May 2010 - continued

SMC website: [www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk)

Medicine	Indication	Local recommendation category	Comments and useful links
Tacrolimus 0.1% ointment (Protopic®) - <i>Full submission</i>	Maintenance treatment of moderate to severe atopic dermatitis for the prevention of flares and the prolongation of flare-free intervals in adult patients (≥16 years) experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected)	<b>Pending specialist feedback</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Telmisartan (Micardis®) - <i>Non submission</i>	Use in cardiovascular prevention (to reduce cardiovascular morbidity in patients with manifest atherothrombotic cardiovascular disease history of coronary heart disease, stroke, or peripheral arterial disease) or type 2 diabetes mellitus with documented target organ damage	<b>Not recommended</b>	<a href="#">SMC advice</a>
Temsirolimus (Torisel®) - <i>Non submission</i>	Treatment of adult patients with relapsed and/or refractory mantle cell lymphoma [MCL]	<b>Not recommended</b>	<a href="#">SMC advice</a>

## Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Darunavir 75mg, 150mg, 300mg, 600mg film-coated tablets (Prezista®) - <i>Abbreviated submission</i>	Co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in highly pre-treated children and adolescents, from the age of 6 years and at least 20kg body weight, who have failed on more than one regimen containing a protease inhibitor (PI)	<b>HOSPITAL ONLY</b> (HIV clinic)  Restricted to use as a second line agent	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Esomeprazole, 40mg vial of powder for solution for intravenous injection or infusion (Nexium I.V.®)- <i>Full submission</i>	Prevention of re-bleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers	<b>HOSPITAL ONLY</b> Local guidance available	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Saxagliptin 5mg film-coated tablet (Onglyza®) - <i>Full submission</i>	Treatment of adult patients with type 2 diabetes mellitus as add-on combination therapy with metformin, when metformin alone, with diet and exercise, does not provide adequate glycaemic control	<b>Non Formulary</b>  Restricted to use in patients only when the addition of sulphonylureas is not appropriate, and represents an alternative to other agents such as thiazolidinediones	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Tipranavir (Aptivus®) 100mg/ml oral solution - <i>Abbreviated submission</i>	In combination with low dose ritonavir for combination antiretroviral treatment of HIV-1 infection in highly pre-treated children from 2 to 12 years of age with virus resistant to multiple protease inhibitors	<b>HOSPITAL ONLY</b> (HIV clinic)  Restricted to initiation by specialists in tertiary centres	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Tipranavir (Aptivus®) 250mg soft capsule - <i>Abbreviated submission</i>	In combination with low dose ritonavir for combination antiretroviral treatment of HIV-1 infection in highly pre-treated adolescents 12 years of age or older with virus resistant to multiple protease inhibitors	<b>HOSPITAL ONLY</b> (HIV clinic)  Restricted to initiation by specialists in tertiary centres	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Ulipristal acetate, 30mg tablet (EllaOne®) - <i>Full submission</i>	Emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure	<b>Formulary</b>  Restricted to use after 72 hours (3 days) and within 120 hours (5 days) of unprotected sexual intercourse if insertion of an IUD is not appropriate or acceptable	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Valganciclovir powder for 50mg/mL oral solution (Valcyte®) - <i>Abbreviated submission</i>	Induction and maintenance treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS)	<b>HOSPITAL ONLY</b> (HIV clinic)	<a href="#">SMC advice</a> <a href="#">SPC link</a>

### SMC Briefing Note:

Click here for [April](#) and [May](#) Briefing Note

## Tayside Area Prescribing Guide (TAPG) Updates – April/May 2010

	TAPG section	Drug(s)/topic	Changes
4.3	Antidepressant drugs	SSRIs	Citalopram now first choice SSRI. Fluoxetine remains on the formulary as a second line choice. Link to <a href="#">SIGN guideline 114, Non-pharmaceutical management of depression in adults, January 2010</a> added.
4.9	Drugs used in Parkinsonism	Introduction	Following a section review, general advice on drug therapy added with a link to <a href="#">SIGN guideline 113, Diagnosis and pharmacological management of Parkinson's disease, January 2010</a> .
		Levodopa	Additional prescribing advice added. Table of preparations available and their drug components inserted.
		Dopamine receptor agonists	New drug class added to formulary. Ropinirole tablets and pramipexole tablets both added as first choice dopamine agonists. Prolonged release ropinirole tablets (Requip <sup>®</sup> XL)▼*, prolonged release pramipexole tablets (Mirapexin <sup>®</sup> Prolonged Release)* and rotigotine transdermal patch (Neupro <sup>®</sup> )▼* are included as minor entries.
		Monoamine-oxidase-B-inhibitors	Change in wording to information on selegiline in line with <a href="#">SIGN guideline 113</a> .
		Catechol-O-methyltransferase inhibitors	New drug class added to formulary. Entacapone tablets and Stalevo <sup>®</sup> tablets* added to formulary. Table of preparations available and their drug components inserted for Stalevo <sup>®</sup> tablets*.
		Antimuscarinic drugs used for extra-pyramidal side effects	Procyclidine and orphenadrine demoted to minor entries. Prescribing advice on antimuscarinic drugs in Parkinson's disease added.
7.3	Contraceptives	Emergency contraception	Ulipristal acetate (EllaOne <sup>®</sup> )▼ 30mg tablets* added to formulary. It is restricted to use between 72 hours (3 days) and 120 hours (5 days) after unprotected sexual intercourse where insertion of an IUD is not appropriate or acceptable. Levonelle <sup>®</sup> (levonorgestrel 1500microgram tablets) remains the first choice of hormonal emergency contraception up to 72 hours (3 days) after unprotected sexual intercourse.
7.4	Drugs for genito-urinary disorders	Antimuscarinic drugs	Oxybutynin standard release preparations added.
13.8	Sunscreens	E45 Sun Block lotion SPF 30+	This has been discontinued. Delph <sup>®</sup> lotion SPF 30 now added.

\*SMC accepted medicine

## [Forthcoming SMC Advice](#)

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.

### **Who produces this bulletin?**

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

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