



## Tayside DTC Supplement No 112 – December 2011

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

### Special points of interest for Primary Care

- Dabigatran - new oral anti-coagulant for non-valvular atrial fibrillation

#### SMC advice:

- Abatacept (Orencia®)
- Adalimumab (Humira®)
- Aprepitant (Emend®)
- Cabazitaxel (Jevtana®)
- Golimumab (Simponi®)
- Naproxen/esomeprazole (Vimovo®)
- Paliperidone (Xeplion®)
- Ranibizumab (Lucentis®)
- Somatropin (Saizen®)
- Dabigatran (Pradaxa®)
- Vardenafil (Levitra®)



## Specialist list - E.N.T.

The Ear, Nose & Throat specialist formulary list has been finalised. Medicines that have been included that may be prescribed under specialist direction are: Ciprofloxacin eye drops (for use in the ear, (unlicensed use)), ipratropium bromide nasal spray, and montelukast tablets.

Other changes to the E.N.T. formulary sections include: addition of Otomize® Ear Spray; azelastine (Rhinolast®) Nasal Spray; mometasone furoate (Nasonex®) Nasal Spray; sodium cromoglycate (Rynacrom®) Nasal Spray; removal of Betnesol® drops and xylometazoline nasal drops; and addition of a new section on laryngopharyngeal reflux (LPR).

[Click here](#) for a link to the E.N.T. specialist formulary list.



## Specialist lists - Progress

The Urology specialist list is being finalised and is due to be published next month. Work is also ongoing to finalise the Gastroenterology specialist list. The Endocrinology, Mental Health and Psychiatry of Old Age specialist lists are under development.



## Drug Safety Updates

Please follow link - [Volume 5, Issue 5, December 2011](#)

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## Prescribing Changes

### Tapentadol prolonged-release tablets (Palexia® SR▼) - Palliative Care Use

Tapentadol prolonged-release tablets may be prescribed by palliative care on completion of an [Individual Patient Treatment Request Form \(IPTTR\)](#). In palliative care modified-release opiates are routinely prescribed with an immediate-release preparation of the same opiate. There are only 2 immediate-release tapentadol oral strengths available, and these do not allow for an appropriate breakthrough dose at total daily doses of tapentadol below 300mg. Tapentadol immediate-release has not been approved by SMC and an IPTTR should be completed for any indication. However, it was agreed on safety grounds, that for any use other than by the chronic pain team or on their recommendations an IPTTR should be completed for prolonged release tapentadol.



## Prescribing Changes - continued

### Dabigatran ( Pradaxa<sup>®</sup>▼ )

Dabigatran is a new oral anticoagulant licensed for the treatment of non-valvular atrial fibrillation. Unlike warfarin, it does not require anti-coagulant monitoring.

Local advice for dabigatran follows a national consensus and restricts use to patients with poor INR control on warfarin, or with allergy to or intolerable side effects from coumarin anticoagulants ([click here](#) for formulary link). Anticoagulant clinics across NHS Tayside will identify eligible patients and make contact with relevant GPs – the clinical decision to transfer these patients to dabigatran will rest with the GP.

Support materials for prescribers include the [SMC advice](#), [national consensus statement](#), [draft patient FAQs](#) and [local guidelines for management of patients on dabigatran](#) (covering conversion to or from parenteral anticoagulants, conversion to or from warfarin, management of bleeding and discontinuation before surgery).

Prescribers should note [recent MHRA advice](#) that renal function should be assessed in all patients before starting dabigatran and while on treatment, renal function should be assessed at least once a year in patients over 75 years of age and whenever a decline in renal function is suspected in any patient. Practices should therefore consider putting normal recall systems in place.

Key drug interactions include: systemic ketoconazole, ciclosporin, itraconazole and tacrolimus - which are contraindicated. Caution should be exercised with other strong P-gp inhibitors (e.g. amiodarone, quinidine or verapamil) refer to [SPC](#) for further details.

Dabigatran is administered as the etexilate salt - a pro-drug which is rapidly converted to the active form (dabigatran) after oral administration. The bioavailability of dabigatran following oral administration is approximately 6.5 % and may be increased by 75 % when the pellets are taken without the hard capsule shell. Therefore, patients should be advised not to open the capsules and take the pellets alone (e.g. sprinkled over food or into beverages).

Dabigatran capsules must remain in the original packaging (blister foil or bottle) until a dose is required. Capsules must be removed from the blister by peeling off the backing foil and should not be pushed through the blister foil. If dabigatran is required in a monitored dosage system (MDS) (e.g. Venalink), the entire unopened blister must be added and the blister size may limit this. The stability of the capsules will be affected if these instructions are not followed, and this may also lead to an increase in bioavailability, gastric adverse effects and bleeding risk of dabigatran.

In-line with ESC guidelines<sup>1</sup>, the local view is that anticoagulation may be considered for patients with a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 1 on a case by case basis taking account of the risks and benefits for the individual. Warfarin remains the first choice agent, note the dabigatran licence does not necessarily cover all patients with a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 1, depending on age and individual risk factors.

<sup>1</sup>Guidelines for the management of atrial fibrillation. The task force for the management of atrial fibrillation of the European Society of Cardiology (ESC). European Heart Journal 2010;31: 2369-1429

### Fulvestrant (Faslodex<sup>®</sup>)

The DTC has approved the use of the oestrogen antagonist fulvestrant (Faslodex<sup>®</sup>) - an SMC 'not recommended' medicine - in a very limited group of patients with advanced metastatic oestrogen positive breast cancer who experience disease progression on or after treatment with tamoxifen and aromatase inhibitors. GPs may prescribe under the direction of the breast cancer clinic.

[Click here](#) for protocol.

Fulvestrant is given by intramuscular injection. A general practice minor surgery fee is available for the administration of fulvestrant.

Medicine	Indication	Local recommendation category	Comments and useful links
Abatacept (Orencia®), 250mg powder for concentrate for solution for injection (618/10) - Abbreviated submission	In combination with methotrexate, for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (JIA) in paediatric patients 6 years of age and older who have had an insufficient response to other disease modifying antirheumatic drugs (DMARDs) <u>including at least one tumour necrosis factor (TNF) inhibitor.</u>	<b>HOSPITAL ONLY</b> (Paediatric Rheumatology Clinic)	<a href="#">SMC Advice</a> <a href="#">SPC link</a>
Adalimumab (Humira®), 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8mL solution for injection vial for paediatric use (738/11) - Abbreviated submission	In combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 4 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.	<b>HOSPITAL ONLY</b> (Paediatric Rheumatology Clinic)	<a href="#">SMC Advice</a> <a href="#">SPC link</a>
Aprepitant 80mg, 125mg hard capsules (Emend®)(242/06) - Resubmission	As part of combination therapy, for prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.	<b>Not recommended</b>	<a href="#">SMC Advice</a>
Cabazitaxel, 60mg concentrate and solvent for solution for infusion (Jevtana®)(735/11) - Full submission	In combination with prednisone or prednisolone, cabazitaxel is licensed for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen.	<b>Not recommended</b>	<a href="#">SMC Advice</a>
Golimumab 50mg solution for injections prefilled pen (auto-injector) or pre-filled syringe (Simponi®) (733/11) - Full submission	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 drug therapy including methotrexate has been inadequate.	<b>HOSPITAL ONLY</b> (Rheumatology Clinic)  <b>Rheumatology specialist list</b>  Restricted to 50mg dose only. Should be used in accordance with BSR guidance on prescribing TNF alpha blockers (2005).	<a href="#">SMC Advice</a> <a href="#">SPC link</a> <a href="#">Rheumatology GP letter - Anti-TNF alpha</a>  This recommendation does not cover golimumab monotherapy.
Naproxen/esomeprazole 500mg/20mg modified release tablets (Vimovo®) (734/11) - Full submission	The symptomatic treatment of osteoarthritis (OA), rheumatoid arthritis (RA) and ankylosing spondylitis (AS), in patients who are at risk for developing non-steroidal anti-inflammatory drug (NSAID)-associated gastric and/or duodenal ulcers and where treatment with lower doses of naproxen or of other NSAIDs is not considered sufficient.	<b>Not recommended</b>	<a href="#">SMC Advice</a>
Paliperidone palmitate 50mg, 75mg, 100mg and 150mg prolonged release suspension for injection (Xeplion®) (713/11) - Resubmission	Maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, it may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed.	<b>HOSPITAL ONLY</b> (General Adult Psychiatry Clinic)  Restricted to use where an atypical antipsychotic is appropriate and depot medication is required due to problems with compliance.	<a href="#">SMC Advice</a> <a href="#">SPC link</a>  Note that oral paliperidone is not recommended by the SMC.

SMC Advice issued in November 2011 - continued.....

Medicine	Indication	Local recommendation category	Comments and useful links
Ranibizumab, 10mg/mL solution for injection (Lucentis <sup>®</sup> ) (732/11) - Full submission	For the treatment of visual impairment due to macular oedema (MO) secondary to retinal vein occlusion (RVO) (branch RVO or central RVO) in adults.	<b>HOSPITAL ONLY</b> (Ophthalmology Clinic)  Restricted to patients with macular oedema secondary to central retinal vein occlusion (CRVO).	<a href="#">SMC Advice</a> <a href="#">SPC link</a>
Somatropin 5.83mg/mL and 8mg/mL solution for injection (Saizen <sup>®</sup> ) (737/11) - Abbreviated submission	See Summary SMC advice for details of indications	GPs may prescribe under the direction of Adult or Paediatric Endocrinology Clinic.	<a href="#">SMC Advice</a> <a href="#">SPC link</a>

Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Dabigatran etexilate 110mg and 150mg hard capsules (Pradaxa <sup>®</sup> ) (672/11) - Full submission	For the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more of the following risk factors: <ul style="list-style-type: none"> <li>• previous stroke, transient ischaemic attack, or systemic embolism</li> <li>• left ventricular ejection fraction &lt;40%</li> <li>• symptomatic heart failure, ≥ New York Heart Association (NYHA) Class 2</li> <li>• age ≥75 years</li> <li>• age ≥65 years associated with one of the following: diabetes mellitus, coronary artery disease or hypertension</li> </ul>	<b>Formulary</b>  Restricted to patients with poor INR control on warfarin, or with allergy to, or intolerable side effects from, coumarin anticoagulants.	<a href="#">SMC advice</a> <a href="#">SPC link (110mg)</a> <a href="#">SPC link (150mg)</a>  <a href="#">NHS HIS Consensus Statement</a>  <a href="#">NHS HIS Patient FAQs</a>  <a href="#">Guidelines for Management of Patients on Dabigatran</a>  <a href="#">Anticoagulant clinic GP letters</a>
Denosumab, 60mg solution for injection in a pre-filled syringe (Prolia <sup>®</sup> ) (651/10) - Full submission	Osteoporosis in postmenopausal women at increased risk of fractures.	GPs may prescribe under the direction of the Osteoporosis Clinic or Medicines for the Elderly.  Restricted to patients with a bone mineral density (BMD) T-score < -2.5 unable to take or continue oral bisphosphonates, strontium ranelate or raloxifene.	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <a href="#">Local protocol</a>  First injection supplied by Osteoporosis Clinic/Medicine For the Elderly (MFE).  A General Practice minor surgery fee is available for the administration of denosumab.
Golimumab 50mg solution for injections pre-filled pen (auto-injector) or pre-filled syringe (Simponi <sup>®</sup> ) (721/11) - Full submission	Treatment of severe, active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy.	<b>HOSPITAL ONLY</b> (Rheumatology Clinic)  <b>Rheumatology Specialist List</b>  Restricted to 50mg dose only. Should be used in accordance with BSR guidance on prescribing TNF alpha blockers (2005).	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <a href="#">Rheumatology GP letter - Anti-TNF alpha</a>



# Tayside Area Formulary (TAF) Updates - Dec 2011

TAF Section	Drug(s)/topic	Changes
Specialist formulary lists	<a href="#">E.N.T.</a>	<a href="#">E.N.T. specialist list</a> added.
	<a href="#">Rheumatology</a>	Golimumab▼ * added to specialist list as 'Hospital Only' and to formulary <a href="#">section 10.1</a> .
	<a href="#">Palliative Care</a>	Local category 'S' removed for hyoscine butylbromide by subcutaneous (SC) injection or continuous subcutaneous infusion (CSCI), levomepromazine 6mg tablets, levomepromazine by SC injection or CSCI, sublingual lorazepam, buccal midazolam, morphine oral and by SC injection or CSCI for breathlessness as these may be initiated and prescribed in General Practice.
<a href="#">1.1</a>	Alginates	Link to formulary <a href="#">section 12.4</a> for treatment of laryngopharyngeal reflux (LPR) added. Indication of LPR added for Gaviscon® Advance suspension.
<a href="#">1.3</a>	PPIs	Link to <a href="#">section 12.4</a> for LPR added. Restricted indication for esomeprazole 40mg daily amended. LPR indication removed as this is covered in <a href="#">section 12.4</a> . Indications for long-term esomeprazole widened to include Barrett's oesophagus or intestinal failure (unlicensed use 'off-label') as well as Zollinger-Ellison Syndrome*.
<a href="#">2.8</a>	Dabigatran▼ *	Dabigatran▼ * added to formulary. See also page 2 of this supplement.
<a href="#">7.3</a>	Contraceptives	Updated information on drug interactions, use of long-acting reversible contraceptive (LARC) methods (hormone releasing intra-uterine system (IUS), intra-uterine devices (IUDs), or implant (Nexplanon®▼ *)). Cilest® and Loestrin 20® removed, Gedarel® 20/150* added. IUDs T-Safe® 380A and Nova-T® 380 added to formulary.
<a href="#">10.1</a>	Golimumab▼ *	Added to formulary as 'Hospital Only' for rheumatoid arthritis (in combination with methotrexate) and ankylosing spondylitis. See also pages 3 & 4 of this supplement.
<a href="#">12.1</a>	Drugs acting on the ear	Removal of Betnesol drops. Addition of Otomize Ear Spray. Addition of Ciprofloxacin eye drops for use in the ear (unlicensed use) to formulary and <a href="#">E.N.T. specialist list</a>
<a href="#">12.2</a>	Drugs acting on the nose	Addition of azelastine nasal spray, certirizine, loratadine, mometasone furoate nasal spray and sodium cromoglycate nasal spray. Addition of ipratropium bromide nasal spray, and montelukast tablets* to formulary and <a href="#">E.N.T. specialist list</a> . Removal of xylometazoline nasal drops. Indication for Naseptin cream added for use post-epistaxis (unlicensed use).
<a href="#">12.3</a>	Drugs acting on the oropharynx	Link to anti-infective sections <a href="#">14</a> & <a href="#">16</a> of formulary for Ear, Nose & Throat infections added.
<a href="#">12.4</a>	Laryngeal Disorders	New section added on treatment of laryngopharyngeal reflux (LPR).

\* SMC accepted medicine

## SMC Briefing Note:

[Click here](#) for November 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.

Please direct any queries to either:

Karen Harkness  
Principal Pharmacist - Clinical Effectiveness  
email: [kharkness@nhs.net](mailto:kharkness@nhs.net)

or

Claire James  
Senior Pharmacist - Clinical Effectiveness  
email: [clairejames@nhs.net](mailto:clairejames@nhs.net)

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