TAYSIDE PRESCRIBER

Tayside DTC Supplement No 97 – June/July 2010
Produced by NHS Tayside Drug and Therapeutics Committee Medicines Advisory Group (MAG)

In this issue:

Minor changes in formulary categories

Minor changes have been made to the formulary categories to improve clarity and to support clinicians in determining what potential place a particular medicine has in the local formulary (the Tayside Area Prescribing Guide known as TAPG). This is likely to be an interim solution pending the development and implementation of a more complete formulary for specialist clinical areas.

A **potential formulary medicine** may now be classified as:

- Formulary – 1st line choice
- Formulary – 2nd line choice
- Formulary - Restricted use – Prescribing or guidance note
- Non-formulary medicine

If an SMC accepted medicine is regarded as a **'Specialist medicine'** then it may be divided into the following categories:

- GPs may prescribe under the direction of a Specialist clinic
- HOSPITAL ONLY (e.g. for use in a Specialist clinic)
- If however, a Specialist does **not** wish to use the medicine locally then the local recommendation would be 'Not routinely recommended in Tayside'.

Links to the amended flowchart for local categorisation of SMC advice and local introduction form can be viewed in a new section of the TAPG website:'Making a formulary application, formulary process and new medicines' under the heading New Medicines - CLICK HERE . The revised categories will be used with immediate effect.

NICE (Multiple) Technology Appraisal Guidance No 188 – Human growth hormone (somatropin) for the treatment of growth failure in children

NHS Quality Improvement Scotland has considered the above appraisal and advises that these recommendations are valid for NHS Scotland. SMC issued guidance to NHS Scotland in 2006 on the use of human growth hormone in children born small for gestational age. NICE MTA guidance supersedes SMC advice. However, the recommendations in the two sets of guidance are consistent.

For copies of the guidance and other related documents go to:
http://www.nice.org.uk/guidance/TA188

Special Points Of Interest

- **Changes in Formulary Categories**
- **Drug Safety Updates**

DRUG SAFETY UPDATES

Carbapenems: concomitant use with valproic acid not recommended

A clinically significant interaction between carbapenems and valproic acid results in reduced valproate plasma concentrations with potential for inadequate seizure control. Concomitant use of these agents is not recommended and prescribers should consider alternative antibacterial therapy. Examples of carbapenems include meropenem, ertapenem, imipenem-cilastin and doripenem. For further information refer to Drug Safety Update Volume 3, Issue 10, May 2010

Quinine: not to be used routinely for nocturnal leg cramps

Overall efficacy of quinine for the treatment of nocturnal leg cramps is modest and there is significant toxicity in overdose. Quinine should only be considered when:

- cramps cause regular disruption of sleep
- cramps are very painful or frequent
- other treatable causes of cramp have been ruled out and
- non-pharmacological measures have not worked (e.g. passive stretching exercises).

After an initial trial of 4 weeks, treatment should be stopped if there is no benefit. Patients should be warned not to exceed the recommended dose. Thrombocytopenia is a rare but potentially life-threatening adverse reaction associated with quinine which should be ruled out if unexplained petechiae, bruising or bleeding occur. For further information refer to Drug Safety Update Volume 3, Issue 11, June 2010

Rivastigmine (Exelon®) transdermal patch: risk of medication errors

Medication errors and inappropriate use of the rivastigmine transdermal patch have been reported, some of which resulted in overdose. Symptoms of rivastigmine overdose include nausea, vomiting, diarrhoea, hypertension and hallucinations; bradycardia and/ or syncope, associated with malaise or falls, may also occur. In case of suspected overdose, all rivastigmine patches should be removed immediately and no further patch should be applied for the next 24 hours.
For further information refer to Drug Safety Update Volume 3, Issue 11, June 2010

It is important to instruct patients and caregivers on the proper use of the transdermal patch.

- Only one patch should be applied per day to healthy skin on the upper or lower back, upper arm, or chest.
- The patch should be replaced by a new one after 24 hours and the previous day's patch must be removed before application of a new patch to a different skin location.
- Application to the same skin location within 14 days should be avoided to minimise skin irritation
- The patch should not be cut in pieces.

SMC Advice issued in June/July 2010

SMC website: www.scottishmedicines.org.uk

Medicine	Indication	Local recommendation category	Comments and useful links
Certolizumab pegol 200mg/ml solution for injection (prefilled syringe) (Cimzia®) - *Full submission*	Treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease modifying anti-rheumatic drugs (DMARDs), including methotrexate, has been inadequate	**Not recommended**	***SMC advice***
Corifollitropin alfa (Elonva®) 100 and 150mcg solution for injection - *Non submission*	Treatment of controlled ovarian stimulation (COS) in combination with a GnRH antagonist for the development of multiple follicles in women participating in an Assisted Reproductive Technology (ART) program	**Not recommended**	***SMC advice***
Epoetin theta 1,000 IU/0.5ml, 2,000 IU/0.5ml, 3,000 IU/0.5ml, 4,000 IU/0.5ml, 5,000 IU/0.5ml, 10,000 IU/1ml, 20,000 IU/1ml, 30,000 IU/1ml solution for injection in pre filled syringe (Eporatio®) - *Full submission*	Treatment of symptomatic anaemia associated with chronic renal failure in adult patients	**HOSPITAL ONLY** **Not routinely recommended in Tayside**	***SMC advice*** ***SPC link***
Ketoprofen/omeprazole 100mg/20mg; 200mg/20mg modified release capsules (Axorid®) - *Resubmission*	Symptomatic treatment of rheumatoid arthritis, ankylosing spondylitis and osteoarthritis in patients with a previous history or who are at risk of developing NSAID associated gastric ulcers, duodenal ulcers and gastroduodenal erosions in whom continued treatment with ketoprofen is essential	**Non-formulary**	***SMC advice*** ***SPC link***
Lapatinib 250mg film-coated tablets (Tyverb®) - *Resubmission*	In combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumours overexpress ErbB2 (HER2) and who have progressive disease following prior therapy including anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting	**Not recommended**	***SMC advice***
Mifamurtide 4mg powder for suspension for infusion (Mepact®) - *Full submission*	In combination with post-operative multi-agent chemotherapy for the treatment of high-grade resectable non-metastatic osteosarcoma after macroscopically complete surgical resection, in children, adolescents and young adults	**Not recommended**	***SMC advice***
Miglustat (Zavesca®) 100mg hard capsules - *Non submission*	Treatment of progressive neurological manifestations in adult patients and paediatric patients with Niemann-Pick type C disease	**Not recommended**	***SMC advice***
Sitagliptin 100mg film-coated tablet (Januvia®) - *Full submission*	As monotherapy, to improve glycaemic control in patients with type 2 diabetes mellitus who are inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance	**Awaiting update of Formulary section 6.1 – Drugs used in diabetes**	***SMC advice*** ***SPC link***

Updates from previous SMC Advice

SMC website: www.scottishmedicines.org.uk

Medicine	Indication	Local recommendation category	Comments and useful links
Beclometasone, formoterol 100/6 (in micrograms) MDI (Fostair®) *-Abbreviated submission*	Treatment of asthma	**Formulary –** restricted use Restricted to use in patients aged 18 years or older on step 3 or above of the BTS/SIGN asthma guidelines	***SMC Advice*** ***SPC link*** ***TAPG Section 3.2***
Fluticasone furoate 27.5 micrograms/actuation nasal spray (Avamys®)- *Full submission*	Treatment of the symptoms of allergic rhinitis in adults, adolescents and children	**Formulary –** 2nd line choice Current first line formulary choice for nasal allergy is beclometasone	***SMC advice*** ***SPC link*** ***TAPG Section 12.2***
Omalizumab 150mg powder and solvent for soluti for injection (Xolair®) - *Abbreviated submission*	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 *in vitro* 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	**HOSPITAL ONLY** (Paediatrics) Local protocol in development	***SMC advice*** ***SPC link***

SMC Briefing Note:

Click here for June/July Briefing Note

Tayside Area Prescribing Guide (TAPG) Updates – June/July 2010

	TAPG section	Drug(s)/Topic	Changes
1.6	Laxatives	Macrogols (Movicol® switch to Laxido® Orange)	Laxido® Orange powder for oral solution has replaced Movicol® powder for oral solution (active ingredient in both macrogol '3350'). Laxido® Orange should be reserved for the treatment of patients with severe constipation unresponsive to first-line laxatives**.** **Please note: Laxido® Orange has been reformulated – it is now Sugar-free and does not contain glucose or sulphur dioxide**. (However existing stock of the original formulation may still be in the supply chain).
3.2	Inhaled corticosteroids	Fostair®▼* (beclometasone/ formoterol)	Fostair®▼*(beclometasone/formoterol) aerosol inhalation added to compound preparations. **Note:** The 100mcg dose of beclometasone in Fostair®▼is **not bioequivalent** to a 100mcg dose of beclometasone in several other inhaler formulations. Fostair®▼has an extra-fine particle size distribution resulting in a more potent effect than formulations of beclometasone with a non extra-fine particle distribution i.e. 100microgram beclometasone in Fostair®▼is equivalent to 250microgram beclometasone in Clenil Modulite®. Fostair®▼is restricted to use in patients aged 18 years or older on step 3 or above of the BTS/SIGN asthma guidelines. Further minor amendments to dose information for medicines throughout section 3.2 made in line with BNF.
10.1	Drugs used in rheumatic diseases and gout	Drugs which suppress the rheumatic disease process	Link to the Tayside Rheumatology website removed as not available while under development.
12.2	Drugs acting on the nose	Fluticasone furoate (Avamys®▼)* (Nasal allergy)	Fluticasone furoate nasal spray (Avamys®▼)* has replaced Fluticasone propionate aqueous nasal spray. Fluticasone furoate is the second line choice of nasal corticosteroid within the TAPG. Beclometasone remains the first choice nasal corticosteroid for nasal allergy.
	Making a formulary application, formulary process and new medicines		New section outlining how to make a formulary application, formulary review process and process for local introduction of new medicines. Includes links to relevant documents.
	Prescribing of medicines for exceptional use – form and policy		New section providing links to the Policy on the Prescribing of Medicines for exceptional use and the form 'Request to prescribe a medicine for exceptional use'.

*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

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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