



Tayside DTC Supplement No 105 – April / May 2011

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

Special points of interest for Primary Care

- Specialist lists - Update
- Atypical antipsychotics

SMC advice:

- Bendamustine (Levact®)
- Calcium acetate /magnesium carbonate tablets (Osveren®)
- Cannabinoid oromucosal spray (Sativex®)
- Drospirenone/ethinylestradiol (Yasmin®)
- Paliperidone prolonged release tablets (Invega®)
- Sevelamer carbonate tablets, suspension (Renvela®)

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Specialist lists - Update

The Renal specialist list is in the process of being finalised and should be added to the Tayside Area Formulary website in the next couple of weeks.

The Palliative Care, Rheumatology and Stroke specialist lists are in development.



Drug Safety Updates

Tigecycline (Tygacil®▼): increased mortality

Analysis of pooled results from clinical trials of tigecycline versus comparator drugs in a range of infections has shown numerically higher mortality rates in patients receiving tigecycline.

Therefore, doctors are advised to use tigecycline only when other antibiotics are unsuitable.

Tayside guidance¹. Tigecycline should only be prescribed on recommendation of Infectious Disease Specialist or Microbiologist, 2nd or 3rd line for complicated skin & soft tissue infections or intra-abdominal infections refractory or intolerant of other usual agents.

Further advice is available from [Drug Safety Update - April 2011](#)

1. Tayside Area Formulary, Section 14. Hospital Antibiotic Policy - Alert Antibiotics

Atypical (second generation) antipsychotics: reminder to manage weight, glucose & lipids

People with schizophrenia are at an increased baseline risk of cardiovascular morbidity and mortality. Some atypical (second-generation) antipsychotics are associated with significant weight gain (>7% of baseline), dyslipidaemia and hyperglycaemia (metabolic adverse effects).

- GPs and primary care health professionals should monitor the physical health of people with schizophrenia at least once a year.
- People with schizophrenia at increased risk of developing cardiovascular disease and / or diabetes (e.g. those with elevated blood pressure, raised lipid levels, smokers, and increased waist measurement) should be identified at the earliest opportunity.

Further advice is available from [Drug Safety Update - April 2011](#) and appropriate NICE guidance 1-4.

1. National Institute for Health and Clinical Excellence. Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease. Clinical guideline 67. 2008. www.nice.org.uk/CG67

2. National Institute for Health and Clinical Excellence. Type 1 diabetes: diagnosis and management of type 1 diabetes in children, young people and adults. Clinical Guideline 15. 2004. www.nice.org.uk/CG15.

3. National Institute for Health and Clinical Excellence. Type 2 diabetes: the management of type 2 diabetes (update). Clinical guideline 66. 2008. www.nice.org.uk/CG66.

4. National Institute for Health and Clinical Excellence. Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children. Clinical guideline 43. 2006. www.nice.org.uk/GC43.

Medicine	Indication	Local recommendation category	Comments and useful links
Bendamustine hydrochloride 25mg, 100mg powder for solution for infusion (Levact®) (694/11) - Full submission	First-line treatment of chronic lymphocytic leukaemia (CLL) (Binet stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate.	Pending* OHMMG decision	SMC advice
Bendamustine 2.5mg/mL powder for concentrate for solution for infusion (Levact®)(700/11) - Non-submission	Front line treatment of multiple myeloma (Durie-Salmon stage II with progress or stage III) in combination with prednisone for patients older than 65 years who are not eligible for autologous stem cell transplantation and who have clinical neuropathy at time of diagnosis precluding the use of thalidomide or bortezomib containing treatment.	Not recommended	SMC advice
Bendamustine 2.5 mg/mL powder for concentrate for solution for infusion (Levact®)(701/11) - Non-submission	Front line treatment of indolent non-Hodgkin's lymphomas as monotherapy in patients who have progressed during or within 6 months following treatment with rituximab or a rituximab containing regimen.	Not recommended	SMC advice
Botulinum toxin type A, 50 unit, 100 unit and 200 unit powder for solution for injection (Botox®)(692/11) - Full submission	Prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine).	Not recommended	SMC advice
Calcium acetate 435mg/magnesium carbonate 235mg tablet (Osvaren®) (693/11) - Full submission	Treatment of hyperphosphataemia associated with chronic renal insufficiency in patients undergoing dialysis (haemodialysis, peritoneal dialysis).	Not recommended	SMC advice
Cannabinoid oromucosal spray (Sativex®) (703/11) - Non-submission	Add-on treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.	Not recommended	SMC advice
Drospirenone/ethinylestradiol, 3mg/30micrograms, film-coated tablets (Yasmin®)(23/03) - Resubmission	Oral contraception.	Not recommended	SMC advice
Paliperidone 1.5mg, 3mg, 6mg, 9mg, 12mg prolonged release tablets (Invega®)(702/11) - Non-submission	Treatment of psychotic or manic symptoms of schizoaffective disorder. Effect on depressive symptoms has not been demonstrated.	Not recommended	SMC advice
Sevelamer carbonate 800mg film-coated tablets and 2.4g of anhydrous powder for oral suspension (Renvela®) (641/10) - Abbreviated submission and resubmission	For the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis.	GPs may prescribe under the direction of the renal clinic Restricted to patients unable to take calcium based phosphate binders as an alternative to sevelamer hydrochloride (Renagel®).	SMC advice SPC link Renal Bone Disease Guidelines under development. Prescribers are reminded to specify sevelamer salt.

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

* OHMMG - Oncology and Haematology Medicines Management Group

And Finally.....

SMC Briefing Note:

[Click here](#) for April 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.

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