

TAYSIDE PRESCRIBER N



Tayside DTC Supplement No 132 – November / December 2013

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



Special points of interest for Primary Care

 Nalmefene - see page 3, awaiting guidance re: counselling

SMC advice:

- Atomoxetine (Strattera[®])
- Axitinib (Inlyta[®])
- Bosutinib (Bosulif[®])
- Canakinumab (Ilaris®)
- Enzalutamide 40mg soft capsules (Xtandi[®])
- Lapatinib (Tyverb[®])
- Ondansetron (Setofilm®)
- Ranibizumab (Lucentis®)
- Sodium phenylbutyrate (Pheburane[®])



Specialist lists - progress

The Parkinson's disease specialist formulary list has been finalised. This list includes medicines that may be prescribed in General Practice, under the direction of a specialist.

Additions to the formulary include: apomorphine; domperidone for postural hypotension associated with dopamine agonists (particularly apomorphine); amantadine; and trihexyphenidyl hydrochloride (benzhexol).

New medicines added to the formulary from this list will not be incorporated into the current core formulary, but will be included in the formulary once launched on the new netFormulary platform.

The <u>Parkinson's disease specialist formulary list</u> can currently be accessed as with other specialist lists from the <u>Tayside Area Formulary</u> website.



Supply problems-tiotropium HandiHaler®

There is a manufacturing problem with tiotropium HandiHaler® (and the refill pand stock is currently limited across the hospitals in NHS Tayside. There is no timescale to where the resolved.

In the interim the following has been approved by the Respiratory

 Start new patients on glycopyrronium in once daily for inhalation

Only switch current patients fro tiotropium HandiHale

bnium inhaler if no stock of

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opyrronium is a powder for inhalation presented in a which dry tered using the Breezhaler® device.

If for teas tients cannot tolerate / use glycopyrronium, then our next choice is aclidinic 22micrograms twice daily) which is available as a dry powder inhaler via the Genuair device.

Please note: tiotropium Respimat[®] is NOT a suitable alternative to the HandiHaler[®] during the manufacturing problem. The Respimat[®] continues to be only approved for use by the respiratory team.

Click Here to access chapter 3.1 (Bronchodilators) of the Tayside Area Formulary.



Drug Safety Updates

Please follow link - <u>Volume 7, Issue 4, November 2013</u>
Please follow link - <u>Volume 7, Issue 5, December 2013</u>



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| SWC Advice issued in November | | Swic website: www.scott | <u></u> |
|---|--|---|--|
| Medicine | Indication | Local recommendation category | Comments and useful links |
| Atomoxetine 10mg, 18mg, 25mg, 40mg, 60mg, 80mg and 100mg capsules (Strattera®) (909/13) - Full submission | Treatment of attention-deficit/ hyperactivity disorder (ADHD) in adults as part of a comprehensive treatment programme. The presence of symptoms that were pre-existing in childhood should be confirmed. | Non-Formulary - protocol pending (GP under direction of Mental Health Specialist) (2nd line) | SMC advice SPC link Shared care agreement under development |
| Axitinib, 1mg and 5mg, film-coated tablets (Inlyta®) (855/13) - Resubmission | For the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine. | Hospital Only (Oncology) Supplied via a Patient Access Scheme | SMC advice SPC link |
| Bosutinib 100mg, 500mg film-coated tablets (Bosulif®) (910/13) - Full submission | Treatment of adult patients with chronic phase, accelerated phase, and blast phase Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options. | Not recommended | SMC advice |
| Canakinumab (llaris®) 150mg powder for solution for injection (926/13) - Non-submission | Treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged two years and older who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate. | Not recommended | SMC advice |
| Enzalutamide 40mg soft capsules (Xtandi®) (911/13) - Full submission | Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy. | Hospital Only (Oncology) Supplied via a Patient Access Scheme | SMC advice SPC link |
| Lapatinib (Tyverb®) 250 mg film-coated tablets (925/13) - Non-submission | Treatment of adult patients with breast cancer, whose tumours overexpress HER2 (ErbB2) in combination with trastuzumab for patients with hormone receptor-negative metastatic disease that has progressed on prior trastuzumab therapy(ies) in combination with chemotherapy. | Not recommended | SMC advice |
| Ondansetron 4mg, 8mg orodispersible films (Setofilm®) (912/13) - Abbreviated submission | In adults: Prophylaxis of acute nausea and vomiting (N & V) induced by moderately emetogenic chemotherapy. Prophylaxis and treatment of delayed N & V induced by moderately to highly emetogenic chemotherapy. Prophylaxis and treatment of acute and delayed N & V induced by highly emetogenic radiotherapy. | Formulary - Haematology / Oncology patients | SMC advice SPC link (4mg) SPC link (8mg) |
| | Prophylaxis and treatment of post-operative nausea and vomiting (PONV). In paediatric populations: Management of chemotherapy-induced N & V in children aged ≥6 months. Prophylaxis and treatment of PONV in children aged ≥4 years. SMC restriction: ondansetron orodispersible films are restricted to use | Non- Formulary Ondansetron liquid preferred Paediatric ward and paediatric haematology/ oncology clinic Restricted to patients with enhanced risk of aspiration or swallowing | |
| | in patients with an enhanced risk of aspiration or who experience difficulties in swallowing. | difficulties who can not tolerate other soluble preparations | |

SMC Advice issued in November 2013 - continued

SMC website: www.scottishmedicines.org.uk

| Medicine | Indication | Local recommendation category | Comments and useful links |
|--|---|---|---------------------------|
| Ranibizumab, 10mg/mL, solution for injection (Lucentis®) (907/13) - Full submission | Treatment for visual impairment due to choroidal neovascularisation secondary to pathologic myopia in adults. | Hospital Only Ophthalmology Specialist List Ist line Supplied via a Patient Access Scheme | SMC advice SPC link |
| Sodium phenylbutyrate granules 483mg/g (Pheburane®) (914/13) - Abbreviated submission | Adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase. | GP under the direction of specialist in metabolic disorders | SMC advice |

'Local processes exist to allow consideration of prescribing outwith SMC advice or outwith NHS Tayside formulary. Details are available in the NHS Tayside Policy on the Prescribing of Medicines that are Non-formulary (including Individual Patient Treatment Requests)'

Updates from previous SMC Advice

| Medicine | Indication | Local recommendation category | Comments and useful links |
|---|---|--|---|
| Bimatoprost 0.3mg/mL plus timolol 5mg/mL, preservative-free, single-dose eyedrops (Ganfort® Unit Dose Preservative Free) (906/13) - Abbreviated submission | For the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical betablockers or prostaglandin analogues. SMC restriction: to use in patients who have proven sensitivity to preservatives. | GP under direction of Ophthalmology Ophthalmology Specialist List Restricted to use in patients who cannot tolerate preservative | SMC advice SPC link Considerably more expensive than latanoprost & timolol plus preservative |
| Nalmefene 18mg film-coated tablets (Selincro®) (917/13) - Full submission | The reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Nalmefene should be initiated only in patients who continue to have a high DRL two weeks after initial assessment. | Non-Formulary - protocol pending | SMC advice SPC link |

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 $^{^{}st}$ 'pending' means that no local recommendation to support use is in place at the current time



Tayside Area Formulary (TAF) Updates - Nov/Dec 2013

| TAF Section | Drug(s)/topic | Changes |
|--|--|---|
| Specialist formulary lists and formulary development | Parkinson's disease | Parkinson's disease specialist formulary list added. |
| 4.6 (netFormulary only)* | Drugs used in nausea and vertigo | Ondansetron orodispersible films (Setofilm®) added to formulary for haematology or oncology patients who cannot take any other oral forms of ondansetron due to enhanced risk of aspiration or swallowing difficulties. |
| 4.6 (netFormulary only)* Parkinson's disease specialist formulary list | Domperidone | Indication for postural hypotension associated with dopamine agonists (particularly apomorphine) [off-label] added to Medicines for the Elderly (MFE) and Parkinson's disease specialist list (under specialist direction). |
| 4.9.1 (net Formulary only)* Parkinson's disease specialist formulary list | Dopaminergic drugs used in Parkinson's disease | Apomorphine and amantadine added to formulary (under specialist direction) and Parkinson's disease specialist list. All dopaminergic drugs used in Parkinson's disease classified as 'Amber' (GPs may prescribe under specialist direction). |
| 4.9.2 (netFormulary only)* Parkinson's disease specialist formulary list | Antimuscarinic drugs used in parkinsonism | Trihexyphenidyl hydrochloride (benzhexol) added to formulary (under specialist direction) and Parkinson's disease specialist list. |
| 11.6 Ophthalmology specialist list | Prostaglandin analogues | Bimatoprost with timolol single-dose eye drops added to formulary (under specialist direction) and Ophthalmology specialist list, restricted to patients who require both components and who cannot tolerate preservative. Bimatoprost with timolol standard eye drops are non-formulary. |
| 11.8.2 Ophthalmology specialist list | Ocular diagnostic, peri- operative preparations and photodynamic treatment | Ranibizumab, I0mg/mL, solution for injection (Lucentis®) added to formulary (Hospital Only) and Ophthalmology specialist list. |

^{*} Tayside netFormulary currently under development and not available for open access.



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.

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<u>CLICK HERE</u> for access to the Medicines Governance section of the Pharmacy Staffnet site.