



## Tayside DTC Supplement No 145 – February 2015

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

### Special points of interest for Primary Care

- Diclofenac
- MHRA Website

### SMC advice - January:

- Aztreonam lysine (Cayston®)
- Bevacizumab (Avastin®)
- Brimonidine (Mirvaso®)
- Canagliflozin plus metformin (Vokanamet®)
- Cetuximab (Erbix®)
- Olodaterol (Striverdi® Respimat®)
- Omalizumab (Xolair®)
- Peginterferon (Plegridy®)

### Inside this issue:

Drug Safety Updates	1
Information Technology	2
SMC Advice issued in January 2015	2-3
Updates from previous SMC Advice	4
TAF Updates	4
SMC Briefing Note	4
Forthcoming SMC Advice	4



## Drug Safety Updates

Please follow link - [Drug Safety Update Download - January 2015](#)  
[Drug Safety Update Download - February 2015](#)

### Diclofenac Tablets no longer available as 'Pharmacy' medicine

Diclofenac 12.5mg (1 x 18) & 25mg tablets (1 x 9) are no longer available from community pharmacies.

Tablets containing diclofenac are now only available as a prescription-only medicine (POM). Topical formulations containing diclofenac will continue to be available without a prescription. In June 2013 a Europe wide review concluded that systemic diclofenac is associated with a small increased risk of serious cardiovascular side effects in some patients, particularly if used at high doses and for long-term treatment. As a result of this review diclofenac was contraindicated in patients with ischaemic heart disease, peripheral heart disease, cerebrovascular disease and congestive heart failure ( NYHA II-IV).

The UK Commission on Human Medicines (CHM) has therefore concluded that patients need to have a medical assessment before taking oral diclofenac to determine if it is suitable for them.

Further information can be found in [Drug Safety Update January 2015 - Oral Diclofenac - Prescription Only](#). [CLICK HERE](#) for Information for Patients.

Cardiovascular contra-indications to diclofenac were detailed in [Tayside DTC Supplement 129 - August/ September 2013](#). Oral diclofenac was removed from the formulary as a result of the MHRA advice and formulary first line choices of non-steroidal anti-inflammatory drugs (NSAIDs) were changed to ibuprofen and naproxen.

A review of NHS Tayside prescribing data in primary and secondary care show a decline in the use of oral diclofenac and a rise in the use of naproxen after the MHRA advice and subsequent Tayside DTC supplement in August 2013. Ibuprofen use has remained fairly steady. In primary care oral naproxen is now prescribed more widely than oral diclofenac. However, in secondary care diclofenac use is still higher than oral naproxen.

Remember oral diclofenac should not be initiated as a routine oral NSAID and is a non-formulary medicine in NHS Tayside for most indications. [CLICK HERE](#) to access the NSAID chapter of the Tayside Area Formulary.



## MHRA Website



The Medicines and Healthcare Products Regulatory Agency (MHRA) website is now on GOV.UK.

The new web address is [www.gov.uk/mhra](http://www.gov.uk/mhra). Bookmarks and saved links to the MHRA's old website should still take you to the information you need. You will automatically be redirected to relevant content on GOV.UK, or to The National Archives, where a copy of the old website has been saved.

The move to GOV.UK won't affect existing online services.

**However, there are currently teething problems with the new site and not all redirected links work.**

You will still be able to access important services, like safety alerts and yellow card reporting.

Drug safety updates are no longer accessible in pdf format. The content of drug safety updates has been broken down into individual safety entries which are searchable from the drug safety update home page using filters at the left hand side. Searches are displayed in date order.

There are approximately 81 links to MHRA drug safety advice from the Tayside Area Formulary. Work is ongoing to ensure these links are updated and working.

**SMC Advice issued in December 2014 (publication date 12 January 2015)**

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

Medicine	Indication	Local recommendation category	Comments and useful links
Aztreonam lysine, 75mg, powder and solvent for nebuliser solution (Cayston®) (753/12) - Resubmission	Suppressive therapy of chronic pulmonary infections due to <i>Pseudomonas aeruginosa</i> in patients with cystic fibrosis aged six years and older. <b>SMC restriction:</b> When inhaled colistimethate sodium and inhaled tobramycin are not tolerated or not providing satisfactory therapeutic benefit (measured as $\geq 2\%$ decline in forced expiratory volume in 1 second [FEV <sub>1</sub> ]).	<b>Formulary</b> GP under direction of specialist Paediatric or Adult CF team <b>Respiratory Specialist List</b>  Supplied via a Patient Access Scheme	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®) (806/12) - Resubmission	In combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics [FIGO] stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer.	<b>Not recommended</b>	<a href="#">SMC advice</a>
Brimonidine, 3.3mg/g (0.33%) gel equivalent to 5mg/g brimonidine tartrate (Mirvaso®) (1016/14) - Full submission	The symptomatic treatment of facial erythema of rosacea in adult patients. <b>SMC restriction:</b> for use in patients with moderate to severe persistent facial erythema associated with rosacea.	<b>Formulary</b> GPs under direction of secondary care (Dermatology) <b>Dermatology Specialist List</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>

cont.

Medicine	Indication	Local recommendation category	Comments and useful links
Canagliflozin plus metformin 50mg/850mg and 50mg/1000mg immediate-release tablets (Vokanamet <sup>®</sup> ) (1019/14) - Abbreviated submission	In adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:  - in patients not adequately controlled on their maximally tolerated doses of metformin alone;  - in patients on their maximally tolerated doses of metformin along with other glucose-lowering medicinal products, including insulin, when these do not provide adequate glycaemic control;  - in patients already being treated with the combination of canagliflozin and metformin as separate tablets.  <b>SMC restriction:</b> use in patients for whom a combination of canagliflozin and metformin is an appropriate choice of therapy.	<b>Formulary</b> For use where a combination of canagliflozin plus metformin is an appropriate choice of therapy.  Triple therapy with insulin <b>(Endocrinology Specialist List)</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <b>Do not initiate in patients with eGFR &lt; 60mL/min. Withdraw if eGFR falls to 45mL/min. Max dose of canagliflozin 100mg daily. Do not use with loop diuretics. Increases levels of digoxin &amp; dabigatran</b>  <b>Twice daily dosing - useful where compliance an issue and patients controlled on set doses</b>
Cetuximab, 100mg/20mL and 500mg/100mL solution for infusion (Erbix <sup>®</sup> ) (1012/14) - Full submission	Treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer:  - in combination with irinotecan-based chemotherapy  - in first-line in combination with FOLFOX;  - as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan.  <b>SMC restriction:</b> for use in patients with RAS wild-type metastatic colorectal cancer, in combination with irinotecan or oxaliplatin-based chemotherapy, in patients who have not previously received chemotherapy for their metastatic disease (first-line treatment).	<b>HOSPITAL ONLY</b> (oncology)  Supplied via a Patient Access Scheme	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Olodaterol 2.5 microgram solution for inhalation (Striverdi <sup>®</sup> Respimat <sup>®</sup> ) (974/14) - Resubmission	Maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease.	<b>Non-formulary</b> - absence of clinician demand	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Omalizumab 150mg solution for injection (Xolair <sup>®</sup> ) (1017/14) - Full submission	As add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.  <b>SMC restriction:</b> use in adults and adolescents with chronic spontaneous urticaria who have an inadequate response to combination therapy with H1 antihistamines, leukotriene receptor antagonists (LTRA) and H2 antihistamines, used according to current treatment guidelines.	<b>HOSPITAL ONLY</b> (Chronic urticaria clinic) <b>Dermatology Specialist List</b>  Supplied via a Patient Access Scheme	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Peginterferon 63, 94 and 125 microgram solution for injection in re-filled syringe (Plegridy <sup>®</sup> ) (1018/14) - Full submission	In adult patients for the treatment of relapsing remitting multiple sclerosis.	<b>HOSPITAL ONLY</b> (Neurology Clinic)	<a href="#">SMC advice</a> <a href="#">SPC link</a> (63 & 94 microgram) <a href="#">SPC link</a> (125 microgram)

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

'Local processes exist to allow 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

No updates this month.



# Tayside Area Formulary (TAF) Updates - Feb 2015

TAF Section	Drug(s)/topic	Changes
<a href="#">03.01.01.01</a>	Long-acting beta <sub>2</sub> agonists - Chronic Obstructive Pulmonary Disease	Olodaterol 2.5 microgram solution for inhalation (Striverdi® Respimat®) - changed from SMC not recommended to non-formulary. See SMC advice on page 3.
<a href="#">03.04.02 Dermatology Specialist List</a>	Omalizumab	New indication added to formulary (Hospital Only) (Red traffic light) and Dermatology specialist formulary list restricted to prescribing by Consultant Dermatologists (chronic urticaria clinic) for use in adults and adolescents with chronic spontaneous urticaria, according to national treatment guidelines. See SMC advice on page 3.
<a href="#">05.01.02.03 Respiratory Specialist List</a>	Other beta-lactam antibiotics	Aztreonam lysine, 75mg, powder and solvent for nebuliser solution (Cayston®) added to formulary (Amber traffic light) and Respiratory specialist formulary list as 3rd line treatment for chronic pulmonary infections due to <i>Pseudomonas aeruginosa</i> in patients with cystic fibrosis (who are intolerant to, or where condition has deteriorated with tobramycin and colistin). See SMC advice on page 2.
<a href="#">05.01.07</a>	Polymyxins	Link to <a href="#">MHRA Drug Safety Update article - Colobreathe: risk of capsule breakage - new instructions for use, November 2014</a> , added to colistimethate sodium (Colobreathe®) entry.
<a href="#">06.01.02.06 Endocrinology Specialist List</a>	Other antidiabetic drugs	Canagliflozin plus metformin 50mg/850mg and 50mg/1000mg immediate-release tablets (Vokanamet®) added to formulary and Endocrinology specialist formulary list (triple therapy with insulin) as per SMC advice - see page 3.
<a href="#">13.6 Dermatology Specialist List</a>	Preparations for Acne and Rosacea	Brimonidine, 3.3mg/g (0.33%) gel equivalent to 5mg/g brimonidine tartrate (Mirvaso®) added to formulary (GPs under the direction of Dermatology) and Dermatology specialist formulary list. See SMC advice on page 2. Links to <a href="#">Isotretinoin Patient Specific Direction</a> (Staffnet intranet link only) updated to current version. Link to <a href="#">MHRA Drug Safety Update article, December 2014 Isotretinoin: reminder of possible psychiatric disorders added</a> .

## SMC Briefing Note:

[Click here](#) for January 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:

David Gill

Lead Clinician - Pharmacoeconomics

email: [david.gill@nhs.net](mailto:david.gill@nhs.net)

or

Claire James

Senior Pharmacist - Clinical Effectiveness

email: [clairejames@nhs.net](mailto:clairejames@nhs.net)

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.