



Tayside DTC Supplement No 123 – January 2013

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

Special points of interest for Primary Care

SMC advice:

- Bortezomib (Velcade®)
- Lanthanum carbonate (Fosrenol®)
- Olmesartan medoxomil/amlodipine besilate/hydrochlorothiazide (Sevikar HCT®)
- Perampanel (Fycompa®)
- Racecadotril (Hidrasec Infants®, Hidrasec Children®)
- Racecadotril (Hidrasec®)
- Ranibizumab, 10mg/mL solution for injection (Lucentis®)
- Sildenafil (as citrate (Revatio®))



Specialist lists - Acute Pain

The [Acute Pain specialist list](#) has been finalised. The list includes treatment and prophylaxis of postoperative nausea & vomiting (PONV); restricted opioids for patient controlled analgesia (PCA) and epidural analgesia as well as epidural step down; restricted opioid analgesics and specialist non opioid drugs for specific pain conditions.

There are links to [NHS Tayside Pain Management Guidelines](#), [NHS Tayside Guideline for prophylaxis and treatment of Post Operative Nausea & Vomiting \(PONV\)](#), [NHS Tayside Epidural Infusion Analgesia Policy and Management Protocols](#) and the [NHS Tayside Guideline on the use of strong opioids in chronic non-malignant pain](#).

Local treatment protocols have been developed for many of the drugs listed. Examples include - [Fentanyl patch for epidural stepdown](#); [oxycodone tablets - restricted use](#), [pregabalin capsules](#), [calcitonin injection](#) and [ascorbic acid tablets](#).



Drug Safety Updates

Please follow link - [Volume 6, Issue 6, January 2013](#)

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Tredaptive®▼ - withdrawal

Tredaptive®▼ modified release tablets - (nicotinic acid / laropiprant) have been withdrawn from the market from immediate effect. The HPS2-THRIVE study has shown that its benefits no longer outweigh its risks. [CLICK HERE](#) for further information.

Tredaptive®▼ was approved by SMC in April 2010. The Tayside recommendation in April / May 2010 was non formulary; GPs may prescribe under the direction of the cardiovascular risk clinic. The drug was restricted to use as monotherapy for the treatment of dyslipidaemia in patients with combined mixed dyslipidaemia and in whom statins were considered inappropriate or not tolerated or both statins and fibrates were considered inappropriate or not tolerated.

The New Medicine link will be updated to inform prescribers in Tayside that the drug has been withdrawn from the market.

[A Class 2 Drug Alert](#) for Tredaptive®▼ modified release tablets was issued on 21-01-13 to recall all unexpired stock.

See [Drug Safety Update: Volume 6, Issue 6, January 2013](#) for further information.



Drug Safety Updates - continued...

Dabigatran (Pradaxa®)

A dear [healthcare professional letter](#) was issued this month from the manufacturers of dabigatran informing prescribers that the drug is now contra-indicated in patients with prosthetic heart valves requiring anticoagulant treatment. The existing warning in section 4.4 not to use dabigatran (Pradaxa®) in patients with prosthetic heart valves is strengthened to a contra-indication based on the availability of new data from clinical trials.

The basis for this SPC change is from the RE-ALIGN trial investigating the use of dabigatran versus warfarin in patients with artificial heart valves. The trial has been stopped as more thromboembolic events and more bleeding events were observed with dabigatran than with warfarin.

The Summary of product Characteristics (SPC) is in the process of being updated.

Current local advice from Cardiology is:

- Other newer anticoagulants [e.g. **rivaroxaban** (Xarelto® ▼) and **apixiban** (Eliquis® ▼)] should also be **AVOIDED** in patients with **prosthetic heart valves**.



Prescribing Changes

Fragmin®

Pfizer has recently incorporated a needle trap safety feature to all UK Fragmin pre-filled syringes (with the exception of the graduated 10,000IU syringe).

This safety measure helps to prevent needle-stick injuries by physically locking away the needle after injection. The syringes still need to be disposed of in a sharps bin as normal.

This follows the European Directive ([Council Directive 2010/32/EU](#)) on preventing sharps injuries in the hospital and health care sector. Therefore these safety devices may appear on other pre-filled syringes in the near future.

The new Fragmin® syringes will be available in the next few weeks - current stocks are required to be used up first.

Please familiarise yourself with the new device by clicking on the following links:

[GENERAL INFORMATION ON THE NEEDLE TRAP DEVICE](#), [DIRECTIONS FOR USE BY HEALTHCARE PROFESSIONALS](#), [DIRECTIONS FOR USE BY PATIENTS](#) and [VTE PATIENT BOOKLET](#) (NHS Tayside Staffnet intranet links only)



Medicine	Indication	Local recommendation category	Comments and useful links
5-aminolaevulinic acid (as hydrochloride), 78mg/g, gel (Ameluz [®]) (811/12) - Full submission	Treatment of actinic keratosis of mild to moderate intensity on the face and scalp (Olsen grade 1 to 2).	HOSPITAL ONLY (Dermatology Clinic) Dermatology specialist list	SMC advice SPC link
Bortezomib (Velcade [®]) 3.5mg powder for subcutaneous injection (822/12) - Abbreviated submission	In combination with melphalan and prednisone for the treatment of patients with previously untreated MM who are not eligible for high-dose chemotherapy with BMT. As monotherapy for the treatment of progressive MM in patients who have received at least one prior therapy and who have already undergone or are unsuitable for BMT.	HOSPITAL ONLY (Haematology) Supplied via a Patient Access Scheme (PAS).	SMC advice SPC link Multiple Myeloma Protocol
Lanthanum carbonate 750mg and 1000mg oral powder (Fosrenol [®]) (821/12) - Abbreviated submission	As a phosphate binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or CAPD. Lanthanum is also indicated in adult patients with chronic kidney disease not on dialysis with serum phosphate levels ≥ 1.78 mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels.	GPs may prescribe under the direction of the Renal Clinic Renal specialist list Restricted to use as second-choice non-calcium based phosphate binder	SMC advice SPC link Sevelamer carbonate is the first-choice non-calcium based phosphate binder in the formulary. Guidelines for the management of bone metabolism and disease in CKD Lanthanum oral powder should be mixed with food
Olmesartan medoxomil / amlodipine besilate / hydrochlorothiazide (Sevikar HCT [®]) (823/12) - Abbreviated submission	In adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation.	Non-formulary - alternatives preferred.	SMC advice SPC link Losartan is the first-choice angiotensin-II receptor antagonist in the formulary. Refer to TAF for guidance on management of hypertension
Perampanel, 2mg, 4mg, 6mg, 8mg, 10mg, 12mg film-coated tablets (Fycompa [®]) (819/12) - Full submission	Adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older.	GPs may prescribe under the direction of the Neurology Clinic. Second-line adjunctive treatment. Restricted to patients with refractory partial onset epilepsy. Supplied via a Patient Access Scheme (PAS).	SMC advice SPC link
Racecadotril 10mg, 30mg granules for oral suspension (Hidrasec Infants [®] , Hidrasec Children [®]) (818/12) - Full submission	Complementary symptomatic treatment of acute diarrhoea in infants older than three months and in children, together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition.	Not recommended	SMC advice
Racecadotril (Hidrasec [®]) 100mg capsules (832/12) - Non-submission	Symptomatic treatment of acute diarrhoea in adults when causal treatment is not possible.	Not recommended	SMC advice
Ranibizumab, 10mg/mL solution for injection (Lucentis [®]) (711/11) - Resubmission	Treatment of visual impairment due to diabetic macular oedema (DMO) in adults.	Pending* specialist feedback	SMC advice SPC link
Sildenafil (as citrate) 20mg film-coated tablets and 10mg/mL powder for oral solution (Revatio [®]) (809/12) - Abbreviated submission	Treatment of paediatric patients aged 1 year to 17 years old with PAH. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease.	GPs may prescribe under the direction of a tertiary centre.	SMC advice SPC link

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

Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Acclidinium 322 micrograms inhalation powder (Eklira Genuair®) (810/12) - Full submission	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	Formulary Restricted to use as third-choice long-acting muscarinic antagonist (LAMA).	SMC advice SPC link Tiotropium Handihaler® is the first-choice LAMA in the formulary.
Collagenase clostridium histolyticum 0.9mg powder and solvent for solution for injection (Xiapex®) (715/11) - Resubmission	Treatment of Dupuytren's contracture in adult patients with a palpable cord.	HOSPITAL ONLY (Plastic Surgery Clinic) Restricted to use as an alternative to limited fasciectomy in patients with Dupuytren's contracture of moderate severity unsuitable for percutaneous needle fasciotomy.	SMC advice SPC link
Fluticasone propionate and formoterol fumarate MDI (Flutiform®) (736/11) - Abbreviated submission	In the regular treatment of asthma where the use of a combination product is appropriate: <ul style="list-style-type: none"> for patients not adequately controlled on ICS and 'as required' inhaled short-acting Beta₂ agonist or for patients already adequately controlled on both ICS and a LABA. 	Formulary	SMC advice SPC link Fostair® (beclometasone/ formoterol) is the first-choice combination inhaler for asthma in the formulary.
Indacaterol 150 and 300 micrograms inhalation powder hard capsules (Onbrez Breezhaler®) (619/10) - Full submission	Maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD).	Formulary First-line long acting B ₂ agonist (LABA) for COPD.	SMC advice SPC link Indacaterol has the advantage of once daily dosing.
Pazopanib 200mg, 400mg film-coated tablets (Votrient®) (676/11) - Full submission	First-line treatment of advanced renal cell carcinoma (RCC) and for patients who have received prior cytokine therapy for advanced disease.	HOSPITAL ONLY (Oncology) Supplied via a Patient Access Scheme (PAS)	SMC advice SPC link Renal cell carcinoma Protocol

'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 \(including Individual Patient Treatment Requests\)](#)'

TAF Section	Drug(s)/topic	Changes
1.5	Treatment of inflammatory bowel disease	Adalimumab ▼* added to the formulary and gastrointestinal specialist list. Hospital only treatment.
2.6	Other antianginal drugs	Ivabradine ▼* - addition to approved use for NYHA class II to IV heart failure. Added to cardiology specialist list. GPs may prescribe under direction of heart failure specialists.
3.1	Bronchodilators	Indacaterol ▼* inhalation powder added to formulary. Formoterol has been removed from the formulary. Glycopyrronium ▼* inhalation powder added to formulary. Aclidinium ▼* inhalation powder added to formulary. Tiotropium (Spiriva Respimat®) ▼* removed from formulary and added to respiratory specialist list - GPs may prescribe under direction of respiratory specialist. Guidance notes on inhaler devices 12 years+ updated.
3.2	Inhaled corticosteroids	Fostair® metered dose inhaler now first line combination LABA/ICS for asthma. Flutiform® ▼* metered dose inhaler added to the formulary. Guidance on Inhaler Devices 12 years+ updated.
13.8	Photodynamic therapy	5-aminolevulinic acid 7.8% gel (Ameluz®) added to formulary and specialist list.

SMC Briefing Note:

[Click here](#) for December 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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