



Tayside DTC Supplement No 127 – May 2013

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

Special points of interest for Primary Care

SMC advice:

April 2013:

- Abatacept (Orencia®)
- Adalimumab, 40mg/0.8mL, solution for injection (Humira®)
- Aflibercept 40mg/mL solution for intravitreal injection (Eylea®)
- Axitinib (Inlyta®)
- Botulinum toxin type A, (Botox®)
- Darunavir oral suspension 100mg/mL (Prezista®)
- Deferasirox (Exjade®)
- Insulin degludec (Tresiba®)
- Insulin glargine (Lantus®, Clikstar®, Lantus® Solostar®)
- Ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®)
- Ruxolitinib (Jakavi®)
- Timothy grass pollen allergen (GRAZAX®)

May 2013:

- Abiraterone (Zytiga®)
- Crizotinib (Xalkor®)
- Lisdexamfetamine dimesylate (Elvanse®)
- Mirabegron (Betmiga®)
- Ranibizumab (Lucentis®)
- Rifampicin, isoniazid, pyrazinamide, ethambutol hydrochloride (Voractiv®)
- Tafamidis meglumine (Vyndaqel®)
- Vildagliptin (Galvus®)
- Vildagliptin/metformin hydrochloride (Eucreas®)

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Specialist lists - progress

The ophthalmology specialist list has been finalised. This list includes several medicines that may be prescribed in General Practice under the direction of a specialist, such as topical steroids for ocular inflammatory conditions, antibiotics for eye infections, treatments for glaucoma, and mydriatics and cycloplegics for anterior and posterior uveitis. There are also a few hospital-only medicines such as topical non-steroidals to reduce post-operative complications, topical antimetabolites to prevent scarring during glaucoma surgery, and ranibizumab for the treatment of visual impairment due to macular oedema/degeneration. See the [specialist formulary list](#) on the Tayside Area Formulary website for full details.

Links have been added to [NICE CG 85](#) Treatment of Glaucoma and Ocular Hypertension as well as several NICE technology appraisals for the use of ranibizumab.



Safer Prescribing Tayside

NHS Tayside is organising its first Medication Safety Week called “Safer Prescribing” from 17th June to 21st June 2013.

A Tayside wide initiative will raise awareness and provide an excellent networking opportunity to build on the good work currently being undertaken around medication safety.

The aims of the week are:

- To increase awareness of key safety issues relating to medication:
 - Medicines Reconciliation
 - High Risk Medicines
 - Polypharmacy
- To promote “Safer Prescribing” campaign materials electronically for all members of staff with key messages about medicines. The TCOE website (www.t-coe.org.uk) will host all this information.
- To promote ‘Not Sure? Just Ask’ campaign materials aimed at encouraging both members of the public and healthcare professionals to ask about medication to improve clarity and understanding for all. These will be distributed to General Practice and Community Pharmacy.

This will be delivered through a program of lunchtime sessions for staff at Ninewells and PRI. There will be stands with material for staff on Level 5, Ninewells (outside doctors mess) and stands with material for patients and public on the concourse, Level 7, Ninewells.

There have been several NPSA alerts for high risk medicines over the last few years and this campaign will be an opportunity to spread awareness of these.

There is an opportunity to highlight the work to date about the new models of care for frail patients that take more than 10 medicines or more (Polypharmacy). The awareness of the national and local Polypharmacy guidelines is important for all staff when reviewing a patient's medicines.



Drug Safety Updates

Please follow link - [Volume 6, Issue 10, May 2013](#)

Dabigatran (Pradaxa®)

In addition to the information we issued in [Tayside DTC Supplement No 123](#), information via [Drug Safety Update](#) (March 2013, Volume 6, Issue 8) from the MHRA has now been issued. They have further updated that dabigatran (Pradaxa®) is contra-indicated in patients with prosthetic heart valves requiring anti-coagulation treatment. As we previously reported, this is due to data from the RE-ALIGN trial which showed an increased frequency of thromboembolic and bleeding events in the group of patients treated with dabigatran, compared with warfarin. There was a higher frequency of either thromboembolic events or bleeding events in patients treated with dabigatran compared with warfarin, regardless of the length of time elapsed since valve implantation.

Updated advice on the timing of using dabigatran after cardiac surgery may be issued when this has been further assessed.

This advice has also been updated in the Summary of Product Characteristics for dabigatran (Pradaxa®).

Local advice from Cardiology continues to be:

- Dabigatran and other newer anticoagulants [e.g. rivaroxaban (Xarelto® ▼) and apixiban (Eliquis® ▼)] should be **AVOIDED** in patients with prosthetic heart valves.
- Dabigatran is non formulary in NHS Tayside.

Aqueous Cream – Skin Irritation in Children With Eczema

A report has been issued by the MHRA detailing the findings that aqueous cream (available over the counter in pharmacies or other retail outlets as a general sale item) may cause skin reactions and irritation in some people, particularly when used as a moisturiser in children who suffer from atopic eczema. These skin reactions may be caused by an ingredient called sodium lauryl sulfate, or other ingredients such as preservatives.

These local skin reactions, such as stinging, burning, itching, and redness, occur when aqueous cream is used as a leave-on emollient, particularly in children with atopic eczema. The reactions, which are not generally serious, often occur within 20 minutes of application but can occur later. Reactions may be due to the presence of sodium lauryl sulfate or other ingredients. If a patient reports or shows signs of skin irritation with the use of aqueous cream, treatment should be discontinued and an alternative emollient that does not contain sodium lauryl sulfate should be tried.

The presumed causative agent, sodium lauryl sulfate (SLS), is contained in emulsifying wax which is one of the ingredients of aqueous cream. SLS functions as a stabiliser and cleansing agent, and is a known skin irritant. However, aqueous cream products often contain other ingredients such as chlorocrescol, cetostearyl alcohol and parabens, which may also cause or contribute to adverse skin reactions.

On the basis of the review, aqueous cream labelling and information leaflet will be updated with a warning on the potential of local skin reactions, and SLS will be listed as an ingredient.

Key advice from the MHRA is:

- Aqueous cream contains sodium lauryl sulfate (SLS) which may cause local skin reactions (eg, stinging and contact dermatitis), particularly in children with atopic eczema. Other ingredients such as preservatives may also contribute to skin reactions.
- During an eczema treatment consultation, health professionals should inform patients that skin irritation (such as burning, stinging, itching or redness) may occur if aqueous cream is used as a leave-on emollient, often within 20 minutes of application.
- If a patient has skin irritation (burning, stinging, itching or redness) after the use of aqueous cream, they should discontinue treatment, and talk to their healthcare professional who will be able to advise on suitable alternative treatments that do not contain SLS.

The review can be found via [MHRA Drug Safety Update Volume 6, Issue 8, March 2013](#) , or in a [MHRA Public Assessment Report](#).



Prescribing Changes

Fostair MART®

Fostair® (beclometasone dipropionate / formoterol fumarate dihydrate) is now licensed in the UK for use as maintenance and reliever therapy (MART) in asthma patients over 18 years old.

Whilst both salmeterol and formoterol are long-acting beta₂-agonists (LABAs), formoterol has a faster onset of action than salmeterol and can be used to relieve bronchoconstriction. (The fluticasone/salmeterol combination inhaler, Seretide®, is unsuitable for use as reliever therapy).

Patients requiring frequent use of rescue inhalations daily should be strongly recommended to seek medical advice. Their asthma should be reassessed and their maintenance therapy should be reconsidered.

Use of a single inhaler as both maintenance and reliever therapy has potential benefits for patients who show poor compliance with traditional asthma treatment regimens involving two or more different inhalers.

Please see [TAF section 3.2](#) for more information.

COPD guidelines

The respiratory Managed Clinical Network (MCN) have updated the NHS Tayside COPD guidelines. Inhaled corticosteroids are now not recommended at step 3, and should only now be introduced at step 4 for a four week trial. If treatment with a corticosteroid is not beneficial it should be stopped. Please see the NHS Tayside [COPD Guidelines](#) for more information.

Rivaroxaban - lifestyle & bleeding advice

The pharmacokinetics of rivaroxaban are affected by food, with the bioavailability increasing from around 66% to almost 100% in the fed state. This only occurs with doses over 10mg daily. **Therefore, rivaroxaban must be taken with food when it is being used for the treatment of PE/DVT or in AF.** For VTE prophylaxis following hip or knee replacement surgery this does not apply.

All patients should be given lifestyle and bleeding advice when commenced on rivaroxaban. The anticoagulation service will not be routinely involved in counselling these patients, either as in-patients or out-patients, so measures must be put in place to ensure they get all the information they need.

There are a number of publications available from the manufacturer:

- Patient brochures for AF, DVT and PE which contain lifestyle advice and FAQs which should be given out with all new rivaroxaban prescriptions. These brochures contain an alert card. All patients on 15mg & 20mg doses **must be given an alert card** and advised to carry it with them at all times.
- Patient information leaflets and alert cards for the 10mg dose which should be given out to patients post hip and knee replacements.
- Prescribing information and a prescribing guide which contain a wealth of useful information including doses, missed doses, conversion from other anticoagulants, peri-operative use and management of bleeding complications.

The brochures contain key information which should be discussed with the patient on initiation of rivaroxaban including:

- ♦ The importance of taking 15mg and 20mg doses with food,
- ♦ The importance of taking doses at the same time each day, and not to miss doses.
- ♦ Side effects including bleeding, and action to take if bleeding occurs.
- ♦ Drug interactions and the importance of informing healthcare professionals that they are prescribed rivaroxaban.
- ♦ The importance of carrying the alert card with them at all times.

These can be found on the [Bayer website](#), but will also be available on relevant wards and pharmacy departments.

Rivaroxaban - dosage change

The SPCs for the 15mg and 20mg tablets have been updated. There is now no requirement to reduce the dose to 15mg after the first 21 days in those with an eGFR 30-49mls/min, unless the risk of bleeding outweighs the risk of further PE or DVT. **If prescribed for AF the dose should still be reduced to 15mg daily in these patients.**

Medicine	Indication	Local recommendation category	Comments and useful links
Abatacept 250mg powder for concentrate for solution for infusion (Orencia [®]) (719/11) - Resubmission	In combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF-alpha inhibitor. SMC restriction: abatacept is restricted for use in patients with active rheumatoid arthritis as measured by disease activity score (DAS28) greater than 5.1 confirmed on at least two occasions, 1 month apart.	Hospital Only Rheumatology Specialist List 4th line agent When response to DMARDs (including at least one TNF-alpha inhibitor) inadequate. Supplied via a Patient Access Scheme (PAS).	SMC advice SPC link Abatacept administration protocol (NHS Tayside Staffnet intranet link only) under development
Adalimumab, 40mg/0.8mL, solution for injection (Humira [®]) (858/13) - Full submission	Treatment of adults with severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis but with objective signs of inflammation by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).	Hospital Only Rheumatology Specialist List	SMC advice SPC link Rheumatology GP letter - Anti-TNF alpha (NHS Tayside Staffnet intranet link only)
Aflibercept 40mg/mL solution for intravitreal injection (Eylea [®]) (857/13) - Full submission	In adults for the treatment of neovascular (wet) age-related macular degeneration.	Non-formulary - alternatives preferred. Supplied via a Patient Access Scheme (PAS).	SMC advice SPC link Ranibizumab is on ophthalmology specialist list for this indication.
Axitinib 1mg and 5mg film-coated tablets (Inlyta [®]) (855/13) - Full submission	For the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.	Not recommended	SMC advice
Botulinum toxin type A, 50 unit, 100 unit and 200 unit powder for solution for injection (Botox [®]) (692/11) - Resubmission	The 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
Darunavir oral suspension 100mg/mL (Prezista [®]) (861/13) - Abbreviated submission	Co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients as well as anti-retroviral therapy (ART)-experienced paediatric patients from the age of 3 years and at least 15 kg body weight. SMC restriction: to be prescribed for patients <18 years under the supervision of specialists in paediatric HIV.	Hospital Only Paediatrics under supervision of HIV paediatricians in Glasgow and Edinburgh.	SMC advice SPC link
Deferasirox (Exjade [®]) 125mg, 250mg and 500mg dispersible tablets (866/13) - Non-submission	Treatment of chronic iron overload requiring chelation therapy when defer-oxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older.	Not recommended	SMC advice
Insulin degludec (Tresiba [®]) 100units/mL solution for injection in pre-filled pen or cartridge and 200units/mL solution for injection in pre-filled pen (856/13) - Abbreviated submission	Treatment of diabetes mellitus in adults.	Not recommended	SMC advice
Insulin glargine 100units/mL solution for injection in a vial, cartridge, pre-filled pen (Lantus [®] , Clikstar [®] , Lantus [®] Solostar [®]) (860/13) - Abbreviated submission	Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. SMC restriction: patients in whom treatment with an insulin analogue is appropriate.	Non-formulary See Tayside links below Diabetes handbook - insulin Paediatric diabetes quick guide	SMC advice SPC link (vial) SPC link (cartridge) SPC link (pen) All insulins non-formulary

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

SMC Advice issued in April 2013

SMC website: www.scottishmedicines.org.uk

Medicine	Indication	Local recommendation category	Comments and useful links
Ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®) (779/12) - Resubmission	Treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy.	HOSPITAL ONLY (Oncology) Supplied via a Patient Access Scheme (PAS).	SMC advice SPC link
Ruxolitinib (Jakavi®) 5mg, 15mg and 20mg Tablets (867/13) - Non-submission	Treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.	Not recommended	SMC advice
Timothy grass pollen allergen (GRAZAX®) 75,000 SQ-T oral lyophilisate (868/13) - Non-submission	Disease-modifying treatment of grass pollen induced rhinitis and conjunctivitis in adults and children (5 years or older), with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen.	Not recommended	SMC advice

SMC Advice issued in May 2013

SMC website: www.scottishmedicines.org.uk

Medicine	Indication	Local recommendation category	Comments and useful links
Abiraterone (Zytiga®) 250 mg tablets (873/13) - Non-submission	Indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.	Not recommended	SMC advice
Crizotinib, 200mg and 250mg, hard capsule (Xalkori®) (865/13) - Full submission	Treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).	Not recommended	SMC advice
Lisdexamfetamine dimesylate, 30mg, 50mg & 70mg capsules (Elvanse®) (863/13) - Full submission	As part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate.	GPs under the direction of child psychiatry. Initiated & stabilized by child psychiatry then GP for prescribing under shared care.	SMC advice SPC link NHS Tayside ADHD shared care pathway <i>Being updated</i>
Mirabegron 25mg and 50mg prolonged-release tablets (Betmiga®) (862/13) - Full submission	Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome.	Formulary 2nd line - oxybutynin is formulary 1st line agent	SMC advice SPC link
Ranibizumab, 10mg/mL solution for injection (Lucentis®) (732/11) - Re-submission	Treatment of visual impairment due to macular oedema (MO) secondary to branch retinal vein occlusion (BRVO) in adults.	Hospital Only Ophthalmology specialist list Supplied via a Patient Access Scheme (PAS).	SMC advice SPC link

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

Medicine	Indication	Local recommendation category	Comments and useful links
Rifampicin, isoniazid, pyrazinamide, ethambutol hydrochloride (Voractiv®) Film-coated Tablets (876/13) - Non-submission	Initial treatment of tuberculosis according to World Health Organisation (WHO) guidelines.	Not recommended	SMC advice
Tafamidis meglumine (Vyndaqel®) 20mg soft capsules (877/13) - Non-submission	Treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment.	Not recommended	SMC advice
Vildagliptin (Galvus®) 50 mg Tablets (875/13) - Non-submission	Treatment of type 2 diabetes mellitus in adults: <ul style="list-style-type: none"> – as triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control – in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control 	Not recommended	SMC advice
Vildagliptin/metformin hydrochloride (Eucreas®) 50 mg/850 mg and 50 mg/1000 mg film-coated tablets(874/13) - Non-submission	Treatment of type 2 diabetes mellitus: <ul style="list-style-type: none"> – in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled with metformin and a sulphonylurea – in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control 	Not recommended	SMC advice

* '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
Cetuximab 100mg/20mL and 500mg/100mL solution for intravenous infusion (Erbix [®]) (543/09) - Re-submission	(EGFR)-expressing, KRAS wild-type metastatic colorectal cancer in combination with chemotherapy.	HOSPITAL ONLY (Oncology) Supplied via a Patient Access Scheme (PAS).	SMC advice SPC link NOSCAN Colorectal Cancer Protocol
Methotrexate injection 10mg/ml (Metoject [®]) (332/06) pre-filled syringes 7.5mg, 10mg, 12.5mg, 15mg, 17.5mg, 20mg, 22.5mg, 25mg - Abbreviated submission	Severe active rheumatoid arthritis in adult patients where treatment with disease modifying drugs (DMARD) is indicated.	GPs may prescribe under the direction of the Rheumatology Clinic. Rheumatology specialist list Methotrexate 10mg/mL discontinued. Use methotrexate 50mg/mL (Metoject [®]) pre-filled syringes 7.5mg, 10mg, 12.5mg, 15mg, 17.5mg, 20mg, 22.5mg, 25mg	SMC advice SPC link Rheumatology GP letter Monitoring in general practice is covered under the Near Patient Testing LES. When administered in general practice, methotrexate inj should be noted under the general practice minor surgery fee. Prescribe by brand name.
Methotrexate injection 50mg/ml (Metoject [®]) (573/09) pre-filled syringes 7.5mg, 10mg, 12.5mg, 15mg, 17.5mg, 20mg, 22.5mg, 25mg - Abbreviated submission	Severe recalcitrant disabling psoriasis in adults not responsive to other forms of therapy such as phototherapy, PUVA, retinoids. Severe psoriatic arthritis in adults.	GPs may prescribe under the direction of Dermatology/ Rheumatology Clinic. Dermatology specialist list Psoriatic arthritis - Dermatology & Rheumatology Specialist Lists	SMC advice SPC link Rheumatology GP letter Dermatology GP letter Monitoring in general practice is covered under the Near Patient Testing LES. When administered in general practice, methotrexate inj should be noted under the general practice minor surgery fee. Prescribe by brand name.



Tayside Area Formulary (TAF) Updates - May 2013

TAF Section	Drug(s)/topic	Changes
1.5	Treatment of inflammatory bowel disease	Modified release mesalazine (Mesren [®] MR) has been re-branded as Octasa [®] . This brand name should now be used for any prescriptions for patients previously on Mesren [®] MR.
3.2	Inhaled corticosteroids	Fostair MART [®] (Maintenance And Reliever Therapy) regimen added to the formulary. Adult Asthma – Inhaled Medicine Chart updated to include Fostair MART [®] .
7.2	Treatment of vaginal and vulval disorders	Estradiol 25microgram vaginal tablets have been discontinued. They have been removed from the formulary. Estradiol 10microgram vaginal tablets have been added to the formulary.
7.3	Contraceptives - progestogen-only	Femulen [®] has been discontinued. It has been removed from the formulary. Cerelle [®] brand has been added to formulary under desogestrel.

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Tayside Area Formulary (TAF) Updates - continued ...

TAF Section	Drug(s)/topic	Changes
7.4.2	Drugs for urinary frequency (in the absence of outflow obstruction), urgency and incontinence	Mirabegron▼ added to the formulary as a second line agent.
10.1.3	Drugs which suppress the rheumatic disease process	Abatacept▼ added to the formulary and rheumatology specialist list. Further indications for adalimumab▼ added to the formulary and rheumatology specialist list. Methotrexate 50mg/mL (Metoject®) pre-filled syringes - GPs can now prescribe under the direction of a specialist for the treatment of severe rheumatoid arthritis and severe psoriatic arthritis.
11	Several additions have been made to the ophthalmology section of the formulary, and the ophthalmology specialist list has been published.	Please see section 11 and the ophthalmology specialist list .
11.8.2	Ocular diagnostic and peri-operative preparations and photodynamic treatment	Ranibizumab▼ has been added to the formulary and ophthalmology specialist list - see SMC advice for indication.
13.4	Topical corticosteroids	Betnovate-C (betamethasone 0.1% and clioquinol 3%) has been discontinued. It has been removed from the formulary. Synalar-C (fluocinolone 0.025% and clioquinol 3%) has been added to the formulary.
13.5.3	Drugs affecting the immune response	Methotrexate 50mg/mL (Metoject®) pre-filled syringes - GPs can now prescribe under the direction of a specialist for the treatment of severe psoriasis and severe psoriatic arthritis.

SMC Briefing Note:

[Click here](#) for May 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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