TAYSIDE PRESCRIBER

Tayside DTC Supplement No 151 – September/October 2015

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

Special Points of Interest for Primary Care

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- **Biosimilar Prescribing Framework**
- **New prednisolone tablet strengths: risk of error**

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- Insulin glargine (Toujeo®)
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Drug Safety Updates

Please follow link - Drug Safety Update Download - September 2015 | October 2015

Proton Pump Inhibitors: subacute cutaneous lupus erythematosus

Proton pump inhibitors (PPIs) are associated infrequently with cases of subacute cutaneous lupus erythematosus (SCLE), a non-scarring dermatosis that can develop in sun-exposed skin sites.

If a patient treated with a proton pump inhibitor (PPI) develops lesions, especially in sun-exposed areas of the skin and it is accompanied by arthralgia:

- Advise them to avoid exposing the skin to sunlight
- Consider subacute cutaneous lupus erythematosus (SCLE) as a possible diagnosis
- Consider stopping use of the PPI unless it is imperative for a serious acid-related condition. A patient who develops SCLE with a particular PPI may be at risk of the same reaction with another
- In most cases, symptoms resolve on PPI withdrawal. Topical or systemic steroids might be necessary for treatment of SCLE only if there are no signs of remission after a few weeks or months

Report any suspected side effect with PPIs, or to any medicine, on a Yellow Card
For further information see Drug Safety Update volume 9 issue 2 September 2015:1

NHS Tayside Photobiology Unit are aware of several local cases of PPI induced SCLE.

Patients with previous SCLE or other autoimmune diseases may be particularly prone to PPI-induced or exacerbated SCLE. There appears to be a higher risk of developing PPI-induced SCLE if patients have anti-Ro antibodies[1]. Patients with known or suspected raised anti-Ro antibodies should probably be advised against use of PPIs.

Drug-induced SCLE can occur weeks, months or even years after exposure to the drug and is more common in elderly female patients. In PPI-induced SCLE, Sandholdt, et al found that the average time from starting the drug to the onset of symptoms was 8 months, which can lead to diagnostic difficulty.

References:

1. Cookson H, Walsh S. Proton Pump inhibitors and subacute cutaneous lupus erythematosus: an under-recognised phenomenon (letter) Br J Dermatol 2014;170:235

2. Sanholdt LH, Laurinaviciene R, Bygum A. Proton pump inhibitor-induced subacute cutaneous lupus erythematosus. Br J Dermatol 2014; 170:342-351

Yellow Card Reporting - Tayside

Yellow Card Reporting via Medicines Information

The Medicines Information (MI) service can support healthcare professionals with reporting adverse drug reactions (ADRs); if an ADR is suspected then healthcare professionals can report the ADR information to MI and, if appropriate, MI will submit a yellow card report directly to the MHRA.

This service is available to all healthcare professionals including hospital doctors, general practitioners, pharmacists in all sectors, non -medical prescribers, nurses and dentists. Healthcare professionals can utilise this service by contacting MI, via **telephone (01382 632351) or e-mail (Tay-UHB.medinfo@nhs.net)**, with the following information:

- Patient details (e.g. age, sex and/or initials)
- Suspected medication (e.g. name and route, dose, indication and/or start/ stop date)
- Suspected reaction and outcome (e.g. reaction resolved or ongoing)
- Any additional information (e.g. other medications in last 3 months)

YellowCard
Helping to make medicines safer

A report can still be submitted even if all of the above information is not available.

The health and financial implications of ADRs are highly significant. **Every healthcare professional has a duty to promote patient safety through pharmacovigilance**; the MHRA Yellow Card Reporting System is the main method of post-marketing surveillance. ADRs are known to be greatly under-reported, both in primary and secondary care. Reasons for this under-reporting may be time restraints and uncertainty regarding when to report an ADR; reporting via MI should help with such issues.

Healthcare professional should report::

- **All suspected ADRs to new medications** (identified with an inverted black triangle next to them in the BNF or SPC). For example, a report should be submitted if a patient suffers diarrhoea following administration of a new vaccine.
- **Any serious* reaction to all other medications** (including prescription medications, vaccines, unlicensed preparations and over the counter and herbal medications). For example, a report should be submitted if a patient develops thrombocytopenia while receiving a well established medication (even if this is already listed as a side effect in the BNF).

* Fatal, life-threatening, disabling, incapacitating or results in or prolongs hospitalisation; **such reactions should be reported even if they are well recognised**.

If there is any doubt regarding whether or not a suspected ADR should be reported, it is always best to report it.

The information obtained through the yellow card system can directly impact on recommendations in the SPC and may even result in the withdrawal of a product from the market. For example, reports of QT prolongation with citalopram and escitalopram have led to new maximum dosing restrictions, contraindications and cautions.

As well as accepting reports via MI centres, yellow card reports can be submitted to the MHRA by post or online.

In addition, **the MHRA recently launched the Yellow Card mobile App** which can be downloaded on Apple (iOS) or Android devices; healthcare professionals can use it to report suspected ADRs and receive up to date information on medicines of interest. CLICK HERE for further information.

Biosimilar Prescribing Framework

The NHS Tayside Drug and Therapeutics committee have endorsed the Healthcare Improvement Scotland document "Biosimilar Medicines: A National Prescribing Framework"

This document provides an overview of Biological and Biosimilar Medicines, how their introduction is being managed by the Scottish Medicines Consortium and issues around prescribing and patient information.

The full document is available on the HIS website at:

http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/programme_resources/biosimilar_medicines_framework.aspx

Prescribing Changes

New prednisolone tablet strengths: risk of error

Prednisolone 10mg and 20mg strength standard tablets are now available. This provides a wider range of prednisolone tablet strengths (in addition to 1mg, 2.5mg, 5mg, and 25mg). However the new 10mg and 20mg strength prednisolone tablets are now non-formulary for Tayside and will not be stocked within Tayside hospitals (secondary care). To minimise the risk of confusion among prescribers and patients the 1mg or 5mg standard tablets are recommended for the majority of prednisolone dosages. The 25mg tablets are significantly more expensive than other standard tablet strengths, however may be required for higher doses of prednisolone.

Prescribers should be particularly careful when prescribing prednisolone tablets to ensure that the correct strength is selected. When dispensing prednisolone tablets ensure that the correct strength is supplied and that patients or carers are aware of the tablet strength(s) supplied. Any change of tablet strength should be highlighted to patients or carers and any change to the number of tablets to be taken.

Medical, nursing, and pharmacy staff within secondary care should be aware of the 10mg and 20mg strength prednisolone tablets (although these strengths of prednisolone tablets will not be available within secondary care) in case patients admitted to hospital are receiving these new strengths of prednisolone. Additional care is therefore required to ensure correct doses are recorded and prescribed on admission. Patients and carers should be made aware of any changes in tablet strength to avoid confusion (e.g. if prednisolone tablet strength supplied on discharge is different to what they have received at home).

Prescribers, Pharmacists, and Nurses should be vigilant regarding prescribing, supply, and administration of prednisolone tablets.

SMC Advice issued in August 2015 (publication date 7 September 2015) **SMC website:**

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Aflibercept (Eylea®) SMC No. (1074/15) *Full Submission*	For adults for the treatment of visual impairment due to macular oedema secondary to branch retinal vein occlusion.	**Formulary** Hospital Only Ophthalmology Specialist Formulary List	***SMC advice*** ***SPC link***
Avanafil (Spedra®) SMC No. (980/14) *Full Submission*	For the treatment of erectile dysfunction (ED) in adult men.	**Not recommended**	***SMC advice***
Bevacizumab (Avastin®) SMC No. (1063/15) *Full Submission*	In combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin for the treatment of adult patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other vascular endothelial growth factor (VEGF) inhibitors or VEGF receptor-targeted agents. SMC Restriction: to use in combination with paclitaxel.	**Non-Formulary** - Pending local decision	***SMC advice*** ***SPC link***

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

Local processes exist to allow prescribing of non-SMC approved medicines for individual patients and are available in the NHS Tayside Policy on the Prescribing of Medicines that are Non-formulary (including Individual Patient Treatment Requests).

SMC Advice issued in August 2015 (publication date 7 September 2015) **SMC website: www.scottishmedicines.org.uk**

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Bortezomib (Velcade®) SMC No. (1075/15) *Full Submission*	In combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation.	**Non-Formulary** - pending local decision	***SMC advice*** ***SPC link***
Darunavir/cobicistat (Rezolsta®) SMC No. (1081/15) *Amended Advice*	In combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years or older. Genotypic testing should guide its use.	**Formulary** Hospital only (HIV Clinic)	***SMC advice*** ***SPC link***
Elosulfase alfa (Vimizim®) SMC No. (1072/15) *Full Submission*	For the treatment of mucopolysaccharidosis, type IVA (Morquio A Syndrome, MPS IVA) in patients of all ages.	**Not Recommended**	***SMC advice***
Enzalutamide (Xtandi®) SMC No. (1066/15) *Full Submission*	For the treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.	**Not Recommended**	***SMC advice***
Eribulin (mesilate) (Halaven®) SMC No. (1065/15) *Full Submission*	For the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.	**Not recommended**	***SMC advice***
Insulin glargine (Toujeo®) SMC No. (1078/15) *Deferred submission*	For the treatment of type 1 or type 2 diabetes mellitus in adults aged 18 years and above. SMC Restriction: Its use should be targeted on patients with Type 1 diabetes who are at risk of or experience unacceptable frequency and/or severity of nocturnal hypoglycaemia on attempting to achieve better hypoglycaemic control during treatment with established insulins. It is also acceptable as a once daily insulin therapy for patients who require carer administration of their insulin. In patients with type 2 diabetes it should be restricted to those who suffer from recurrent episodes of hypoglycemia or require assistance with their insulin injections.	**Non-Formulary** - absence of clinician demand	***SMC advice*** ***SPC link***
Ketoconazole (Ketoconazole HRA®) SMC No. (1100/15) *Non Submission*	For the treatment of endogenous Cushing's syndrome in adults and adolescents above the age of 12 years.	**Not recommended**	***SMC advice***

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SMC Advice issued in August 2015 (publication date 7 September 2015) **SMC website: www.scottishmedicines.org.uk**

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Ledipasvir/sofosbuvir (Harvoni®) SMC No. (1084/15) *Full Submission*	For the treatment of genotype 3 chronic hepatitis C (CHC) in adults. SMC Restriction: patients who are ineligible for or unable to tolerate interferon.	**Formulary** Hospital Use Only (Hepatitis C clinic)	***SMC advice*** ***SPC link***
Lisdexamfetamine dimesylate (Elvanse Adult®) SMC No. (1079/15) *Deferred submisison*	Part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in adults.	**Non-Formulary** - absence of clinician demand	***SMC advice*** ***SPC link***
Pasireotide (as pamoate)(Signifor®) SMC No. (1048/15) *Deferred submission*	For the treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with another somatostatin analogue.	**Non-Formulary** - pending local agreement	***SMC advice*** ***SPC link***
Sitagliptin (Januvia®) SMC No. (108315) *Full Submission*	For the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycaemic control.	**Formulary** - GPs may prescribe under direction of the Diabetes team.	***SMC advice*** ***SPC link***
Tafluprost/timolol (Taptiqom®) SMC No. (1085/15) *Abbreviated Submission*	For the reduction of intraocular pressure in adult patients with open angle glaucoma or ocular hypertension who are insufficiently responsive to topical monotherapy with beta-blockers or prostaglandin analogues and require a combination therapy, and who would benefit from preservative-free eye drops.	**Non-Formulary** - lack of clinician support	***SMC advice*** ***SPC link***
Tigecycline (Tygacil®) SMC No. (1101/15) *Non submission*	Treatment in children from the age of eight years for the following infections: - complicated skin and soft tissue infections, excluding diabetic foot infections complicated intra-abdominal infections.	**Not recommended**	***SMC advice***

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

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Updates from previous SMC Advice - No updates this month.

Tayside Area Formulary (TAF) Updates - Sep/Oct 2015

TAF Section	Drug(s)/topic	Changes
Specialist Formulary Lists	Cardiology	Links to Amiodarone tablets (Adults) Shared Care Agreement and Patient Information Leaflet added.
	Epilepsy	Epilepsy Specialist formulary list added. Includes medicines for epilepsy approved for prescribing by or on the recommendation of a prescribing neurology specialist. Further details of corresponding formulary changes are listed below under TAF section 04.08.01 and 04.08.02.
01.03.05	PPIs	Note added that PPIs are associated infrequently with cases of subacute cutaneous lupus erythematosus (SCLE), a non-scarring dermatosis that can develop in sun-exposed skin sites. Link to article from Drug Safety Update, September 2015 added for further information.
01.05.02	Prednisolone	Note added that 10mg and 20mg strength prednisolone tablets are non-formulary. See page 3 for further information.

Tayside Area Formulary (TAF) Updates - Sep/Oct 2015

TAF Section	Drug(s)/topic	Changes
02.03.02	Amiodarone	Links to Amiodarone tablets (Adults) Shared Care Agreement and Patient Information Leaflet added. Link to MHRA Drug Safety Update - Simeprevir with sofosbuvir: risk of severe bradycardia and heart block when taken with amiodarone, August 2015 added.
02.08.02	Stroke prevention in AF	Tayside Approach to Thromboprophylaxis for patients with non-valvular AF - interim update regarding information on drug interactions and prescribing in patients at extremes of weight. The Tayside Approach to Thromboprophylaxis for patients with non-valvular AF is expected to receive further review soon.
04.08.01	Control of epilepsy	Link to SIGN guideline 143 Diagnosis and management of epilepsy in adults, May 2015 added. Additional prescribing information added throughout section including advice on drug interactions with antiepileptic drugs, particularly with hormonal contraceptives. Link to Faculty of Sexual & Reproductive Healthcare guidance on interactions with hormonal contraceptives added. The following medicines have been added as Amber traffic light (GPs may prescribe under specialist direction): oxcarbazepine, eslicarbazepine, ethosuximide, lacosamide, perampanel, phenobarbital, retigabine, tiagabine, vigabatrin, zonisamide, and clobazam. The following medicines have been changed from Green to Amber traffic light: carbamazepine, lamotrigine, phenytoin, topiramate, and sodium valproate.
04.08.02	Drugs used in status epilepticus	Link to SIGN guideline 143 Diagnosis and management of epilepsy in adults, May 2015 added. The following medicines have been added as Red traffic light (Hospital Only): phenytoin IV, sodium valproate IV, and levetiracetam IV. Links to local protocols for management of status epilepticus in adults in General Practice (community) or hospital (inpatient) added.
04.09.01	Dopamine receptor agonists - Restless legs	Ropinirole, pramipexole, and rotigotine drug entries updated with restless legs as an indication/condition that GPs may initiate treatment for (Green traffic light). Link to Restless legs syndrome (RLS) / Willis-Ekbom disease (WED) treatment algorithm added to drug entries for ropinirole, pramipexole, and rotigotine.
05.03.01	Darunavir/cobicistat (Rezolsta®)	Added to formulary as Hospital Only (HIV Clinic) as an alternative to darunavir (Prezista®) plus ritonavir (Norvir®) where HIV protease inhibitor therapy is required (in adults).
05.03.03.02	Chronic hepatitis C	Ledipasvir/sofosbuvir (Harvoni®) indication for use in treatment of genotype 3 chronic hepatitis C (CHC) in adults added to Gastroenterology specialist formulary list (Hospital Only (Hepatitis C Clinic)).
06.01.02.04	Sitagliptin	Sitagliptin as add-on to insulin (with or without metformin) for type 2 diabetes mellitus added to Endocrinology specialist formulary list - GPs may prescribe under direction of the Diabetes team.
06.03.02	Prednisolone	Note added that 10mg and 20mg strength prednisolone tablets are non-formulary. See page 3 for further information.
09.02.01.01	Calcium Resonium®	Sorbisterit® (polystyrene sulphonate resins) discontinued, replaced with Calcium Resonium® (polystyrene sulphonate resins).
10.01.02.01	Prednisolone	Note added that 10mg and 20mg strength prednisolone tablets are non-formulary. See page 3 for further information.
11.08.01	Liquid paraffin eye ointment (Xailin Night®)	Liquid paraffin eye ointment (VitA-POS®) discontinued, replaced with Xailin Night® eye ointment (liquid paraffin, white soft paraffin).
11.08.02	Subfoveal choroidal neovascularisation	Aflibercept (Eylea®) - indication for treatment of visual impairment due to macular oedema secondary to branch retinal vein occlusion added to Ophthalmology specialist formulary list (Hospital Only).
13.05.02	Preparations for psoriasis	Sub-sections for Scalp psoriasis have been created. Addition of the following medicines: Betamethasone valerate 0.12% foam, hydrocortisone butyrate 0.1% lotion (Locoid Crelo®), Dovobet® gel, Dermovate® scalp application, Clarelux® foam, Etrivex® shampoo, Tacalcitol lotion (Curatoderm®), Emulsiderm® liquid emulsion, olive oil, coconut oil, dithranol (Dithrocream® and Micanol®). Removal of the following: Calcipotriol scalp solution (now non-formulary as significantly more expensive than other treatment options).

SMC Briefing Note: September

Forthcoming SMC Advice

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.

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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