



Special Points of Interest for Primary Care

SMC Advice - October:

- Abiraterone acetate (Zytiga®)
- Budesonide (Cortiment®)
- Ciclosporin (Ikervis®)
- Empagliflozin plus metformin (Synjardy®)
- Everolimus (Afinitor®)
- Insulin degludec/liraglutide (Xultophy®)
- Midodrine hydrochloride (Bramox®)
- Nintedanib (Ofev®)
- Radium-223 dichloride (Xofigo®)
- Trastuzumab (Herceptin®)
- Travoprost (Travatan®)

SMC Advice - November:

- Atazanavir/cobicistat (Evotaz®)
- Bevacizumab (Avastin®)
- Edoxaban (Lixiana®)
- Edoxaban tosylate (Lixiana®)
- Everolimus (Certican®)
- Pembrolizumab (Keytruda®)
- Raltegravir (Isentress®)
- Regorafenib (Stivarga®)
- Tiotropium/olodaterol (Spiolto® Respimat®)
- Triamcinolone (Hexacetonide®)



Drug Safety Updates

Please follow link to Drug Safety Updates for - [November 2015](#) and [December 2015](#).

Mirabegron (Betmiga ▼): risk of severe hypertension and associated risks

Mirabegron is restricted to use in patients who are unable to tolerate or who have had an unsatisfactory response to antimuscarinics, for the treatment of urinary incontinence. It has been approved for use in NHS Tayside as a 2nd line formulary medicine since 2013.

Hypertension is a recognised but uncommon side effect (1 in 100) and blood pressure should be monitored at baseline and periodically during treatment, especially in hypertensive patients.

A European wide review of the safety of mirabegron has highlighted cases of severe hypertension, including hypertensive crisis associated with reports of cerebrovascular and cardiac events (mainly transient ischaemia attack or stroke).

Main Points

- Mirabegron is now contraindicated in patients with severe uncontrolled hypertension (systolic blood pressure ≥ 180 mm Hg or diastolic blood pressure ≥ 110 mm Hg, or both)
- Use mirabegron with caution in patients with systolic blood pressure ≥ 160 mmHg or diastolic blood pressure ≥ 100 mm Hg
- Monitor blood pressure at baseline and periodically during treatment with mirabegron, especially in hypertensive patients

See [Summary of Product Characteristics](#) for further information including dosing in renal & hepatic impairment and important drug interactions.

Further information can be found in [Drugs Safety Update October 2015](#)

Note: mirabegron ▼ is a relatively new drug. All suspected ADRs associated with new drugs identified by the black triangle ▼ should be reported to the MHRA yellow card scheme, either directly or locally, via Tayside Medicines Information service:

Tay-UHB.medinfo@nhs.net .

Mirabegron has been updated to an amber traffic light (under direction of Urology) in the Tayside Area Formulary.

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Drug Safety Updates - cont.

Nicorandil - Risk of Ulcerations and Progression to Complications

A 'Dear Healthcare Professional' letter in November has highlighted the risk of ulcerations and potential complications with nicorandil. This follows reviews by European medicines regulatory agencies of the risk of skin and mucosal ulceration with nicorandil and the indications for its use. GI ulceration with nicorandil was previously reported in [Drug Safety Update June 2008](#).

Key recommendations:

- Nicorandil is now indicated for treatment of stable angina only in patients whose angina is inadequately controlled by 1st line anti-anginal therapies or who have a contraindication or intolerance to first line anti-anginal therapies such as beta-blockers and or calcium antagonists.
- Nicorandil can cause serious skin, mucosal, and eye ulceration, which persists unless treatment is discontinued.
- Stop nicorandil treatment if ulceration develops on any part of the body. If stopping nicorandil treatment worsens angina symptoms, consult a cardiologist.
- Gastrointestinal ulcers may progress to perforation, haemorrhage, fistula or abscess.
- Patients with diverticular disease may be at particular risk of fistula formation or bowel perforation compared with patients without diverticular disease.
- Taking aspirin, non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids concomitantly with nicorandil increases the risk of gastrointestinal ulceration, perforations, and haemorrhage compared with taking either medicine alone.
- Nicorandil is now contraindicated in hypovolaemia, acute pulmonary oedema and for use with soluble guanylate cyclase stimulators such as riociguat.
- Use nicorandil with caution in combination with medicines which increase potassium levels, especially in patients with moderate to severe renal impairment

The 'Dear Healthcare Professional' letter can be accessed [here](#), or from the Ikorel® (nicorandil) Summary of Product Characteristics from the [electronic Medicines Compendium](#) (eMC).

The nicorandil entry in the Tayside Area formulary has been updated with a summary of the above recommendations.



Specialist List Updates

Palliative Care Specialist Formulary List

The [Palliative Care Specialist Formulary List](#) within the [Tayside Area Formulary](#) has been reviewed and updated. Less medicines are listed in the specialist formulary list than before as most medicines are already included within the [Scottish Palliative Care Guidelines](#). Please refer to the Scottish Palliative Care Guidelines website for evidence based or best-practice guidance on a range of common clinical issues for the management of adult patients with life-limiting illness, including: advice and information on specific medicines; pain management; symptom control; palliative emergencies; end of life care; subcutaneous infusion of medication and compatibility of drugs that can be given subcutaneously via a syringe driver. The Scottish Palliative Care Guidelines website is easily accessible as a link from the Tayside Area Formulary [homepage](#).



Prescribing Changes

Lithium Carbonate (Camcolit® 250mg) Proprietary Name Change

Lithium carbonate (Camcolit®) 250mg tablets have been renamed to 'Lithium Carbonate Essential Pharma 250mg tablets'. The strength and formulation remain the same. Camcolit® 400mg prolonged release tablets have not been rebranded. As lithium should be prescribed by brand name due to differing bioavailability between products, patients taking Camcolit® 250mg tablets should be informed of the proprietary name change and lithium cards and lithium treatment booklets should be updated where appropriate.

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Abiraterone acetate 250mg tablets (Zytiga®) SMC No. (873/13) Independent Review Panel Accepted	Indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.	Non Formulary Pending local Agreement	SMC advice
Budesonide 9mg prolonged release tablets (Cortiment®) SMC No. (1093/15) Abbreviated Submission Not Recommended	For use in adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where 5-ASA treatment is not sufficient.	Not Recommended	SMC advice
Ciclosporin 1mg/mL (0.1%) eye drops emulsion (Ikervis®) SMC No. (1089/15) Full Submission Accepted	For treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes.	Formulary GP under direction of Ophthalmology (Corneal Clinic)	SMC advice SPC link
Empagliflozin plus metformin 5mg/850mg, 5mg/1000mg, 12.5mg/850mg, 12.5mg/1000mg film-coated tablets (Synjardy®) SMC No. (1092/15) Abbreviated Submission Accepted restricted	For use 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 inadequately controlled on their maximally tolerated dose of metformin alone - in patients inadequately controlled with metformin in combination with other glucose-lowering medicinal products, including insulin - in patients already being treated with the combination of empagliflozin and metformin as separate tablets. SMC restriction: for use in patients for whom this fixed dose combination of empagliflozin and metformin is considered appropriate. For use as dual therapy (empagliflozin and metformin) when a sulphonylurea is inappropriate.	Non Formulary Absence of Clinician demand	SMC advice
Everolimus 2.5mg, 5mg and 10mg tablet (Afinitor®) SMC No. (872/13) Re-submission assessed under the end of life process Not Recommended	For the treatment of hormone receptor-positive, HER2/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor.	Not Recommended	SMC advice
Insulin degludec/liraglutide 100 units/mL / 3.6mg/mL solution for injection pre-filled pen (Xultophy®) SMC No. (1088/15) Full Submission Accepted restricted	Treatment of adults with type 2 diabetes mellitus to improve glycaemic control in combination with oral glucose-lowering medicinal products when these alone or combined with a GLP-1 receptor agonist or with basal insulin do not provide adequate glycaemic control. SMC restriction: for use in patients who are uncontrolled on basal insulin analogues (glycosylated haemoglobin [HbA1c] >7.5% [59mmol/mol]) and for whom a GLP-1 receptor agonist is appropriate as an add-on intensification therapy to basal insulin to obtain glucose control.	Formulary GP under direction of Diabetes Clinic	SMC advice SPC link

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

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

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Midodrine hydrochloride 2.5mg, 5mg tablets (Bramox®) SMC No. (1094/15) Abbreviated Submission Accepted	For use in adults for the treatment of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate.	Non Formulary Pending local protocol under development	SMC advice
Nintedanib 100mg and 150mg capsules (Ofev®) SMC No. (1076/15) Full Submission assessed under the orphan process Accepted restricted	For use in adults for the treatment of idiopathic pulmonary fibrosis (IPF). SMC restriction: For use in patients with a predicted forced vital capacity (FVC) less than or equal to 80%.	Non Formulary Pending protocol review	SMC advice
Radium-223 dichloride 1000kBq/mL solution for injection (Xofigo®) SMC No. (1077/15) Full submission assessed under the end of life and orphan process Accepted	For the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases.	Non Formulary Absence of Clinician demand	SMC advice
Trastuzumab 150mg powder for concentrate for solution for infusion (Herceptin®) SMC No. (623/10) Second re-submission considered under the ultra-orphan and end of life process Accepted restricted	In combination with capecitabine or fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease. It is indicated for use only in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay. SMC restriction: for use in patients whose tumours have HER2 overexpression defined by immunohistochemistry (IHC) 3+ ("HER2 high expresser").	Non Formulary Pending local agreement	SMC advice
Travoprost 40 micrograms/mL eye drops (Travatan®) SMC No. (1091/15) Abbreviated Submission Accepted	Decrease of elevated intraocular pressure in paediatric patients aged 2 months to <18 years with ocular hypertension or paediatric glaucoma.	Formulary GP under direction of ophthalmology/paediatrics	SMC advice SPC link

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Atazanavir/cobicistat 300mg/150mg film-coated tablets (Evotaz®) SMC No. 1098/15 Abbreviated submission Accepted	In combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults without known mutations associated with resistance to atazanavir.	Formulary Hospital Use only (HIV clinic)	SMC advice SPC link
Bevacizumab 25mg/mL, concentrate for solution for infusion (Avastin®) SMC No. 806/12 2nd Resubmission Accepted restricted	In combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics (FIGO) stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. SMC restriction: In patients with FIGO stage IV disease.	Non Formulary Pending local Agreement	SMC advice

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Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Edoxaban tosilate 15mg, 30mg, 60mg film-coated tablets (Lixiana®) SMC No. 1090/15 Full submission Accepted	Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.	Non Formulary	SMC advice
Edoxaban tosilate 15mg, 30mg and 60mg film-coated tablets (Lixiana®) SMC No. 1095/15 Full submission Accepted	Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAf) with one or more risk factors, such as congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA).	Non Formulary Pending local agreement	SMC advice
Everolimus 0.25mg, 0.5mg and 0.75mg tablets (Certican®) SMC No. 1117/15 Non-submission Not Recommended	Prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving a cardiac transplant. Prophylaxis of organ rejection in patients receiving a hepatic transplant.	Not Recommended	SMC advice
Pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®) SMC No. 1087/15 Full submission Not Recommended	As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously treated with ipilimumab.	Not Recommended	SMC advice
Pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®) SMC No. 1086/15 Full submission Accepted	As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously untreated with ipilimumab.	Non Formulary Pending local Agreement	SMC advice
Raltegravir granules for oral suspension 100mg (Isentress®) SMC No. 1102/15 Abbreviated submission Accepted restricted	In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults, adolescents, children, toddlers and infants from the age of 4 weeks. SMC restriction: patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir granules should be prescribed under the supervision of specialists in paediatric HIV.	Formulary Hospital Use (HIV and Paediatrics only)	SMC advice SPC link
Raltegravir chewable tablets 25mg, 100mg (Isentress®) SMC No. 1113/15 Abbreviated submission Accepted restricted	In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in children from the age of 4 weeks to <2 years. SMC restriction: patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug interactions; raltegravir chewable tablets should be prescribed under the supervision of specialists in paediatric HIV.	Formulary Hospital Use (HIV Paediatrics only)	SMC advice SPC link

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Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Regorafenib 40mg film-coated tablets (Stivarga®) SMC No. 1118/15 Non-submission Not Recommended	Adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies.	Not recommended	SMC advice
Tiotropium/olodaterol 2.5 microgram/2.5 microgram inhalation solution (Spiolto® Respimat®) SMC No. 1099/15 Abbreviated submission Accepted	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	Formulary	SMC advice SPC link
Triamcinolone 20mg/ml suspension for injection (Hexacetonide®) SMC No. 1103/15 Abbreviated submission Accepted	Juvenile idiopathic arthritis (JIA).	Formulary Hospital Use only (Paediatric rheumatology and orthopaedics)	SMC advice SPC link

Updates from previous SMC Advice

Medicine	Indication	Local Recommendation	Comments and Useful Links
Tedizolid phosphate 200mg film-coated tablets and 200mg powder for concentrate for solution for infusion (Sivextro®) SMC No. (1080/15) Full submission Accepted restricted	Use in adult patients with acute bacterial skin and skin structure infections (ABSSSI). SMC restriction: - ABSSSI caused by Gram-positive <i>Staphylococcus aureus</i> (specifically methicillin-resistant <i>Staphylococcus aureus</i> [MRSA] isolates). - Tedizolid phosphate is restricted to use as an alternative oxazolidinone antibacterial on the specific advice of local microbiologists or specialists in infectious disease.	Non-formulary	SMC advice
Rufinamide 40mg/ml oral suspension (Inovelon®) SMC No. (795/12) Abbreviated submission Accepted restricted	Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age or older. SMC restriction: restricted to use in patients who have failed treatment with or are intolerant of other antiepileptic drugs.	GPs under the direction of Paediatric Neurology Clinic	SMC advice SPC link
Rufinamide 100mg, 200mg and 400mg tablets (Inovelon®) SMC No. (416/07) Resubmission Accepted restricted	Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age or older. SMC restriction: to use in patients who have failed treatment with or are intolerant of alternative traditional antiepileptic drugs.	GPs under the direction of Paediatric Neurology Clinic	SMC advice SPC link

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Tayside Area Formulary (TAF) Updates - Nov 2015

TAF Section	Drug(s)/Topic	Changes
Specialist Formulary Lists	Dermatology	5-fluorouracil 1% cream in unguentum M cream (unlicensed special) added to the Dermatology specialist formulary list for Hospital Only prescribing in Darier's disease (keratosis follicularis).
	Palliative Care	Palliative Care specialist formulary list reviewed and updated. Medicines removed that are already within the Scottish Palliative Care Guidelines . Duloxetine (Cymbalta®) and lidocaine infusion added to the Palliative Care specialist formulary list in line with the Chronic Pain Specialist formulary list. See page 2 for further information.
	Renal	Renal Specialist formulary list reviewed and the following changes have been undertaken this month: removal of Methoxy polyethylene glycol-epoetin beta (Micera®), calcium acetate (PhosLo®), and sevelamer hydrochloride (Renagel®). Indication amended for cyclophosphamide tablets. Indication expanded for mycophenolate mofetil, azathioprine, tacrolimus and ciclosporin. Link to guidance on medical management of adult patients with ESKD undergoing parathyroidectomy added for alfacalcidol entry.
02.06.03	Nicorandil	Now restricted to symptomatic treatment of patients with stable angina who are inadequately controlled or have a contraindication or intolerance to first-line antianginal therapies (such as beta-blockers and/or calcium antagonists). This is further to the risk of ulcerations and progression to complications with nicorandil. See page 2 for further information.
02.07	Midodrine	Licensed midodrine tablets now available. Non-formulary entry updated to include licensed preparation. See SMC advice on page 4 for further information.
Chapter 3	Useful links	Removal of previous Guidance on inhaler devices 12 years +, as this was out of date. Relevant information from this previous guidance has been incorporated into a new sub-section 03.01.05 - see below.
03.01.04	Compound bronchodilator preparations	Spiolto Respimat® added to the formulary as Green traffic light as an option for patients with COPD at Step 3 as per Inhaled Medicine Chart for COPD . See SMC advice on page 6.
03.01.05	Spacer devices	AeroChamber Plus® and Volumatic® from previous Guidance on inhaler devices for 12 years +, now formulary entries. Relevant information from previous guidance incorporated into the notes section of this new formulary sub-section.
03.02	Compound preparations - asthma	Budesonide and formoterol dry powder for inhalation (DuoResp Spiromax®) added to formulary as Green traffic light option for combined ICS/LABA in asthma steps 3-5 as per Inhaled Medicine Chart Asthma . Symbicort Turbuhaler® and Seretide Accuhaler® now non-formulary.
03.02	Compound preparations - COPD	Budesonide and formoterol dry powder for inhalation (DuoResp Spiromax®) added to formulary as Green traffic light option for COPD as per Inhaled Medicine Chart COPD . Seretide Accuhaler® now non-formulary. Note added that the place of combined ICS/LABA in COPD is limited to those patients with more severe disease, and those having 2 or more exacerbations over a 12 month period (i.e. frequent/regular exacerbators).
04.02.01	Haloperidol injection	Link to memo on haloperidol injection shortage added.
04.02.03	Lithium carbonate	Information on rebranding of lithium carbonate 250mg tablets added. See page 2 for further information.
04.07.01	Nefopam	Wording of formulary indication clarified as reserved for patients who have a proven contraindication, intolerance or a poor response to both opioid and NSAID analgesia or on advice of the Pain team, following nefopam supply shortage.
04.07.02	Morphine	Link to Breathlessness guideline from the Scottish Palliative Care Guidelines added.
04.07.02	Fentanyl nasal spray (PecFent®)	Restricted to patients unsuitable for Abstral® added to formulary entry for clarification of local formulary status.
04.07.03	Ketamine	Controlled drug symbol added as now a Schedule 2 controlled drug. Link to Tayside Prescriber Issue 136 - Ketamine Rescheduling to Schedule 2 Controlled Drug added.

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TAF Updates - Nov 2015 - cont.

TAF Section	Drug(s)/Topic	Changes
05.01.07	Some other antibacterials	Sivextro® (tedizolid phosphate) added to formulary as Hospital-Only use: restricted to only under ID/ microbiology advice (Alert Antibiotic). Only licensed for skin and soft tissue infection and for a maximum 6 days duration. See previous SMC advice on page 6.
05.03.01	HIV infection	Evotaz® (atazanavir/cobistat) and Isentress® (raltegravir) added to formulary as Hospital-Only (Red Traffic light) by HIV clinic. See SMC advice on page 4 and 5.
06.01.02.05	Glucagon-like peptide-1 receptor agonists	Insulin degludec/liraglutide 100 units/mL / 3.6mg/mL solution for injection pre-filled pen (Xultophy®) added to formulary as a note within liraglutide entry and added to the Endocrinology Specialist formulary list (Amber traffic light) (prescribing by GPs under direction of the diabetic clinic). See SMC advice on page 3.
07.04.02	Mirabegron	New contra-indications added to formulary entry and a link to the MHRA Drug Safety Update - Mirabegron: risk of severe hypertension and associated cerebrovascular and cardiac events, October 2015 . See page 1 for further information.
08.02.01	Antiproliferative immuno-suppressants	Additional indication 'Maintenance of remission of ANCA associated systemic vasculitis and SLE nephritis following induction therapy with cyclophosphamide or rituximab ' added for mycophenolate mofetil and azathioprine.
08.02.02	Corticosteroids and other immunosuppressants	Additional indication 'Maintenance of remission of nephrotic syndrome' added for tacrolimus [off-label] and ciclosporin.
09.01.03	Erythropoietin	Methoxy polyethylene glycol-epoetin beta (Mircera®) now non-formulary.
09.05.02.02	Phosphate-binding agents	Calcium acetate (PhosLo®) discontinued - now non-formulary and annotated as discontinued. Sevelamer hydrochloride (Renagel®) now non-formulary, generic sevelamer carbonate preferred.
09.06.04	Vitamin D	Alfacalcidol - link added to medical management of adult patients with ESKD undergoing parathyroidectomy guidance.
11.08.01	Tear deficiency, ocular lubricants, and astringents	VitA-POS® added back into formulary as not discontinued. Xailin Night® remains in formulary as an alternative to VitA-POS® if it is unavailable. Ciclosporin 1mg/mL (0.1%) eye drops emulsion (Ikervis®) added to formulary and Ophthalmology Specialist formulary list (Amber traffic light) for severe keratitis in adults with dry eye disease in addition to tear substitutes. This has replaced the previous ciclosporin 2% eye drops which were unlicensed. See SMC advice on page 3.

SMC Briefing Note: [November 2015](#)

[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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