



Tayside DTC Supplement No 126 – April 2013

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

Special points of interest for Primary Care

- Rivaroxaban for PE
- Palliative care formulary - on line access

SMC advice:

- Bevacizumab (Avastin®)
- Bimatoprost (Lumigan UD®)
- Infliximab (Remicade®)
- Ingenol mebutate (Picato®)
- Rivaroxaban (Xarelto®)
- Sugammadex (Bridion®)



Specialist lists - progress

The specialist lists for ophthalmology and haematology/oncology are nearing completion and should be finalised in May. The epilepsy specialist list is underway and will hopefully be presented to MAG in June.



Guidelines and Protocols

Antimicrobial Guidance Update

NEW GUIDELINES

There have been 2 new guidelines added to the Antimicrobial Website (Section 5 TAF) :

Antibiotic Lady: This guideline gives recommendations on how to treat infections seen in pregnancy, the post natal period and when breast feeding.

Chronic Wounds and Ulcers: As well as guidance on which anti-microbials to prescribe there is useful information on how to assess infection, which organisms are most likely to be colonizers and links to relevant sections of the Wound Management Formulary.

UPDATED GUIDELINES

The following guidelines have been reviewed and updated :

- ◆ Penicillin Hypersensitivity Guidance
- ◆ Hospital Paediatric Empirical Treatment of Infection Guidelines (Antibiotic Teddy)
- ◆ Empirical Treatment of Infection in Renal Patients
- ◆ Treatment of a first episode of Clostridium difficile infection and recurrent infection.

ANTIMICROBIAL PHARMACY TEAM CONTACT DETAILS:

Due to staff changes please use the new email address below if you wish to contact any member of the team:

Tay-UHB.antibioticpharm@nhs.net

Inside this issue :

Specialist lists - progress 1

Guidelines & Protocols 1

Drug Safety Updates / Drug Alerts 1-2

Prescribing Changes 2

Information Technology 2

SMC Advice issued in March 2013 3

TAF Updates 4

SMC Briefing Note 4

Forthcoming SMC Advice 4

Desunin® protocol finalised

The vitamin D (Desunin®) protocol has been finalised. This gives guidance on when to measure vitamin D levels, when to commence replacement therapy and the recommended dosing regimen. It also contains information on lifestyle advice, common dietary sources of vitamin D and at risk groups who may require maintenance therapy. [Click here](#) for local guidance.



Drug Safety Updates / Drug Alerts

Please follow link - [Volume 6, Issue 9, April 2013](#)

Calcitonin (Miacalcic®) nasal spray

Further to the information provided in [Tayside DTC Supplement No 120](#), there has been a Drug Alert Class 2 Medicines Recall from the MHRA detailing that action should be taken within 48 hours to recall all stock of Miacalcic® 200 IU Nasal Spray Solution. All unexpired stock of this product is being recalled to pharmacy, clinic and wholesaler level irrespective of batch number and expiry date.

This product has now been withdrawn from the market. No further Miacalcic® 200 IU Nasal Spray Solution should be dispensed. Pharmacists should refer patients with new or repeat prescriptions to the treating physician to review their treatment plan on a non-urgent basis.

Calcitonin (Miacalcic®) nasal spray (continued..)

Healthcare professionals should no longer prescribe calcitonin nasal spray .

Remaining stocks of the affected batches should be quarantined and returned to the original supplier for credit.

Further information can be found at [MHRA Drug Alert](#) and the original [MHRA Drug Safety Update Aug 2012, Volume 6, Issue 1, August 2012](#).



Prescribing Changes

Sodium bicarbonate

Sodium bicarbonate 8.4% pre-filled syringes (Minijets) have been discontinued by the manufacturer. There is currently no equivalent product available.

Sodium bicarbonate 8.4% is not recommended in resuscitation guidelines and the NHS Tayside Cardiopulmonary Resuscitation (CPR) Committee have agreed that it is not required in the blue CPR boxes. The CPR boxes now being issued do not contain sodium bicarbonate 8.4%.

If there is a clinical requirement for intravenous sodium bicarbonate 8.4% in your ward or department, it is still available in a 200ml Polyfusor for intravenous infusion. However, there are manufacturing problems with all strengths of sodium bicarbonate Polyfusors (1.26%, 4.2% and 8.4%). All products currently have a maximum shelf-life of one month. Frequent expiry date checks and replenishment of expired products will be necessary until the problems are resolved.

Rivaroxaban

Rivaroxaban's license has been extended to cover treatment of pulmonary embolism (PE) and deep vein thrombosis (DVT), as well as prevention of recurrent PE and DVT in adults. Locally, use is not recommended for periods of greater than 12 months for these indications due to a lack of experience with use beyond this time frame.

There are several drug-drug interactions to be aware of, most notably rifampicin (plasma rivaroxaban levels reduced), some antifungals (plasma rivaroxaban levels increased) and certain anti-virals. Please see [BNF – rivaroxaban \(drug interactions\)](#) for more information. In patients with moderate renal impairment (eGFR 30-49mL/min) the dose should be reduced. Locally not recommended for use in those with eGFR <30mL/min due to limited trial data. Please see [TAF section 2.8](#) for dosing information.

Please note: using above maximum licensed doses of rivaroxaban (see SPC links -15mg and 20mg) is not recommended, nor is using rivaroxaban in conjunction with any other anticoagulant. Any deviations from this MUST go through the Individual Patient Request (IPTR) process.

For information on changing patients from warfarin or parenteral anticoagulants to rivaroxaban, as well as how to manage bleeding and discontinuation prior to surgery, please see the [Guidelines for Management of Patients on Rivaroxaban or Apixaban](#).



Information Technology

Palliative Care Formulary

The Palliative Care Formulary (PCF) provides essential information for prescribers involved in palliative and hospice care. *

It brings together authoritative independent guidance on best practice with clinically validated drug information, and thus helps to ensure that drugs are used appropriately, safely, and optimally. The PCF is currently in its 4th print edition and is regularly revised online to provide the most up to date content.

Access is now available free of charge to those with an NHS Education Scotland ATHENS username and password through the new Palliative Care Portal on The Knowledge Network (www.knowledge.scot.nhs.uk/). You will need to log in with your Athens user name and password to access the content.

Click on the Portals and Topics link at the top of the home page then the Palliative Care link or use following link:

<http://www.knowledge.scot.nhs.uk/home/portals-and-topics/palliative-care.aspx>

*note: PCF often used in addition to [NHS Scotland Palliative Care Guidelines](#) which are accessible from the home page of TAF.

| Medicine | Indication | Local recommendation category | Comments and useful links |
|---|--|--|---|
| Bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®) (853/13) - Full submission | Bevacizumab, in combination with carboplatin and gemcitabine, is indicated for treatment of adult patients with first recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents. | Not recommended | SMC advice |
| Bimatoprost 0.3mg/mL single-dose eye drops (Lumigan UD®) (839/13) - Abbreviated submission | Reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults (as monotherapy or as adjunctive therapy to beta-blockers). SMC restriction: to use in patients who have proven sensitivity to the preservative benzalkonium chloride. | Non-Formulary - alternatives preferred | SMC advice SPC link Bimatoprost with preservative is an alternative to latanoprost not requiring refrigeration. |
| Infliximab 100mg powder for concentrate for solution for infusion (Remicade®) (854/13) - Full submission | Treatment of severely active ulcerative colitis in children and adolescents aged 6 to 17 years who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies. SMC restriction: as an alternative to ciclosporin in patients with acute, severe paediatric ulcerative colitis (rescue therapy) who are steroid refractory. | Hospital Only (Paediatric ward / clinic) Alternative to ciclosporin | SMC advice SPC link SSPGHAN protocol Infliximab protocol (paediatric) Risk of infusion reaction - observe for 2 hours after the end of every infusion. Monitoring undertaken by secondary care. |
| Ingenol mebutate, 150 & 500micrograms/g, gel (Picato®) (851/13) - Full submission | Cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults. | Formulary | SMC advice SPC link (150mcg) SPC link (500mcg) Short duration of treatment (2 or 3 days). |
| Rivaroxaban 15mg and 20mg film-coated tablets (Xarelto®) (852/13) - Full submission | Treatment of pulmonary embolism (PE), and prevention of recurrent deep vein thrombosis (DVT) and PE in adults. | Formulary - 1st line choice GPs may prescribe under the direction of secondary care (Ninewells medical assessment area, respiratory, vascular, PRI medical admissions). Max duration 12 months, confirmed PE. | SMC advice SPC link (15mg) SPC link (20mg) PE protocols being updated Not recommended in patients with GFR < 30mL/min. |
| Sugammadex 100mg/mL (1mL, 2mL, 5mL) solution for injection (Bridion®) (527/09) - Re-submission | Reversal of neuromuscular blockade induced by rocuronium or vecuronium. For the paediatric population: sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents. This re-submission is for the part of the indication relating to routine reversal of neuromuscular blockade. SMC restriction: only for use in the routine reversal setting in high-risk patients (e.g. morbid obesity, significant respiratory disease or reduced respiratory reserve, significant coronary disease, major abdominal/chest surgery) or where prompt reversal of neuromuscular block is required. | Hospital Only (Anaesthetics) Restricted for the routine reversal of neuromuscular blockade in a selected group of patients / circumstances as per local guidance. | SMC advice SPC link Sugammadex Policy |

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

| TAF Section | Drug(s)/topic | Changes |
|--|--|--|
| 2.8 | Anticoagulants | New indications for rivaroxaban ▼ added to the formulary. |
| 6.4.1 | Female sex hormones and their modulators | Ulipristal acetate ▼ 5mg tablets added to formulary and endocrinology specialist list. |
| 13.7 | Preparations for warts | Salactol paint® replaces Salatac® gel as first line preparation on the formulary for the treatment of warts, corns and calluses. Salatac® gel has been removed from the formulary. |
| 13.8 | Sunscreens and photodamage | Ingenol mebutate ▼ 150micrograms/g & 500 micrograms/g gels have been added to the formulary. |
| Wound Management Formulary | Introduction | Information on the processes of the Wound Management Formulary Group added. |
| | Section 1 | List of formulary dressings updated. |
| | Section 1.1 | List of specialist dressings updated. |
| | Section 1.3 | Wound product evaluation form added. |

SMC Briefing Note:
[Click here](#) for April 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:

Karen Harkness
Principal Pharmacist - Clinical Effectiveness
email: kharkness@nhs.net

or

Clare Balfour
Specialist Pharmacist - Clinical Effectiveness
email: clarebalfour@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.