TAYSIDE PRESCRIBER

NHS Tayside

Tayside DTC Supplement No 120 – October 2012

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

Special points of interest for Primary Care

- Calcitonin nasal spray
- Simvastatin & amlodipine or diltiazem

SMC advice:

- Colecalciferol (Fultium-D_3®)
- Fingolimod (Gilenya®)
- Tegafur/gimeracil/oteracil (Teysuno®)
- Tocilizumab (RoActemra®)
- Vemurafenib (Zelboraf®)

Inside this issue :

Guidelines and Protocols

Dronedarone▼ - updated protocol

Further to advice in the July 2012 Drug Safety Update on dabigatran▼ , Dabigatran is now contraindicated with dronedarone. The dronedarone protocol has been updated to include this information.

Use of liraglutide or exenatide with insulin

Local advice to support the use of exenatide as an adjunctive therapy to basal insulin in adults with type 2 diabetes was issued in DTC Supplement No 119.

Use of exenatide or liraglutide in combination with basal-bolus insulin is covered in a separate local protocol - click here

Unlicensed medicines - responsibilities

The responsibility that falls on healthcare professionals when prescribing an unlicensed medicine or a medicine "off-label" is greater than when prescribing a licensed medicine within the terms of its marketing authorisation.

Prescribers should pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine "off-label".

These risks may include: adverse reactions; product quality; or discrepant product information or labelling e.g. absence of information for some unlicensed medicines, information in a foreign language for unlicensed imports and potential confusion for patients or carers when the Patient Information Leaflet is inconsistent with a medicine's off-label use.

Unlicensed medicines or medicines used outwith their marketing authorisation ('off-label') use will be annotated in the specialist formulary lists next to the medicine name or indication.

For unlicensed medicines or medicines used 'off-label' the quality, safety and efficacy will not have been evaluated and the **risk of use rests with the prescriber**.

Click here for further information.

Drug Safety Updates

Please follow link - Volume 6, Issue 2, September 2012

Prescribing Changes

Calcitonin nasal spray - to be withdrawn

The European Medicines Agency has recently completed a review of the benefits and risks of calcitonin concluding that there was evidence from randomised controlled trials of an increased risk of malignancies with the long term use of calcitonin compared with placebo treated patients. As a result of this finding calcitonin should no longer be used in the treatment of established post-menopausal osteoporosis, since the risks associated with calcitonin outweigh the benefits in this indication. Calcitonin nasal spray (Miacalcic®) which is only licensed for the treatment of post-menopausal osteoporosis will be withdrawn from the European market.

- **Patients currently being treated with intra-nasal calcitonin for osteoporosis should be reviewed and changed to another suitable treatment.**
- **Calcitonin nasal spray is non formulary in NHS Tayside for the treatment of post menopausal osteoporosis.**

Calcitonin nasal spray will be removed from the Endocrinology and Medicines for the Elderly specialist list for the off-label use of pain from osteoporotic fractures and in acute vertebral fracture. Patients currently on calcitonin nasal spray for these indications will be reviewed and switched to alternative treatment.

Calcitonin will still be available as a solution for injection and infusion for the short-term treatment of:

- Paget's disease – now restricted to patients who do not respond to, or cannot tolerate, alternative treatments (ie, patients with renal impairment). Duration of calcitonin should be limited to up to 3 months, but may be extended to 6 months under exceptional circumstances (e.g., patients with impending pathologic fractures)
- acute bone loss prevention due to sudden immobilisation, for up to 4 weeks only (no change in use)
- hypercalcaemia of malignancy (no change in use)

In all remaining indications, treatment with calcitonin should be limited to the shortest possible time, using the minimum effective dose.

Refer to Drug Safety Update Aug 2012 volume 6, issue 1 for further information.

Simvastatin: decrease in maximum dose with amlodipine & diltiazem

A Tayside Prescriber has been written which outlines the updated drug interaction with statins. The maximum licensed dose of simvastatin with either amlodipine or diltiazem is now 20mg.

Recommended statins for patients taking amlodipine, diltiazem, verapamil or amiodarone on simvastatin or requiring a statin at their next routine appointment are:

- primary prevention - simvastatin 20mg daily or atorvastatin 10mg daily;
- secondary prevention - atorvastatin 20mg daily and titrate as necessary (ensure lowest necessary dose of atorvastatin used with diltiazem, verapamil or amiodarone).

Patients with diabetes currently prescribed **simvastain 40mg** in combination with amlodipine or diltiazem should be switched to **atorvastatin 20mg.**

Click here to access advice for patients on 'Simvastatin: why your dose or treatment may have recently changed'. This is the first article from the MHRA on a patient version o f a drug safety update article.

Medicine	Indication	Local recommendation category	Comments and useful links
Colecalciferol 800 international units (equivalent to 20 micrograms vitamin D_3) capsules (Fultium-D_3®) (801/12) - *Full submission*	In adults, the elderly and adolescents for the prevention and treatment of vitamin D deficiency and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.	Pending* specialist feedback	***SMC advice***
Fingolimod (as hydrochloride), 0.5mg hard capsules (Gilenya®) (763/12) - *Re-submission*	As single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups: - Patients with high disease activity despite treatment with a beta-interferon; **OR** - Patients with rapidly evolving severe RRMS.	Pending* specialist feedback	***SMC advice***
Tegafur/gimeracil/oteracil 15mg/4.35mg/ 11.8mg and 20mg/5.8mg/15.8mg hard capsules (Teysuno®) (802/12) - *Full submission*	Treatment of advanced gastric cancer when given in combination with cisplatin.	Patients unsuitable for first-line triple therapy: Non-formulary - absence of clinician support Patients suitable for first-line triple therapy: **Not recommended**	***SMC advice*** ***SPC link (15mg)*** ***SPC link (20mg)*** Mitomycin C and 5-FU are alternative options for patients unsuitable for ECF/ X or EOX - ref ***Upper GI Cancer Protocol***
Tocilizumab, 20mg/mL, concentrate for solution for infusion (RoActemra®) (774/12) - *Re-submission*	Tocilizumab monotherapy is indicated in patients who are intolerant to methotrexate or where continued treatment with methotrexate is inappropriate, for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.	**HOSPITAL ONLY** (Rheumatology Clinic) **Rheumatology Specialist list** Restricted to use in accordance with BSR guidance. Supplied via a Patient Access Scheme (PAS).	***SMC advice*** ***SPC link*** First-line biologic in patients unable to tolerate methotrexate or in whom continued methotrexate is inappropriate.
Vemurafenib 240mg film-coated tablet (Zelboraf®) (792/12) - *Full submission*	As monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.	**Not recommended**	***SMC advice***

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

OHMMG - Oncology and Haematology Medicines Management Group

'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)'

Tayside Area Formulary (TAF) Updates - Oct 2012

TAF Section	Drug(s)/topic	Changes
Specialist formulary lists and formulary development	Palliative Care	***Link to online palliative care formulary removed (no longer free access) for hydromorphone (unlicensed), ketorolac (off-label), methadone and methylnaltrexone▼* injections. Contact local palliative care services for further advice added for these 4 medicines including specific contact details for each locality.***
	Endocrinology & Medicine for the Elderly	***Calcitonin nasal spray (Miacalcic®) removed from Endocrinology and Medicine for the Elderly specialist lists and 6.6 Drugs affecting bone metabolism section of the formulary***
	Rheumatology	***Use of tocilizumab as monotherapy added to rheumatology specialist list and section 10.1 Drugs used in rheumatic diseases and gout.***
	Unlicensed medicines…	***Guidance on the responsibilities of unlicensed & off-label medicines added into section on 'Using the Tayside Area Formulary' and each Specialist formulary list.***
1.5	Prednisolone rectal foam	***Predfoam® discontinued. Brand name removed. Prescribe generically.***
2.12	Lipid regulating drugs	***Advice regarding updated statin interactions added including specific advice for simvastatin and use with amlodipine, diltiazem, amiodarone or verapamil.***
4.7.4	Antimigraine drugs	***Section updated. Additional information on prophylaxis of migraine added. 1st choice for migraine prophylaxis now includes propranol or amitriptyline. Alternative beta blockers to propranolol added. Dose information expanded for propranolol and venlafaxine. Additional cautions / contraindications added to table for prophylactic therapies. Link to patient information leaflets for migraine on staffnet added.***
4.8	Anti-epileptic drugs	***Epanutin® capsules brand no longer available. Name has been changed to phenytoin sodium Flynn hard capsules. Epanutin® brand name removed from formulary.***

* = SMC accepted medicine

SMC Briefing Note:

Click here for September 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

Jan Jones
Principal Pharmacist - Pharmacoeconomics
email: janjones@nhs.net