

TAYSIDE PRESCRIBER



Tayside DTC Supplement No 94 – December 2009/January 2010

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



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Bisphosphonates – change in local prescribing advice

The following **revised** advice has been added to the TAPG:

Oral bisphosphonates should be used with caution in patients with active or recent oesophageal or upper GI problems. Alendronate is contraindicated and risedronate should be used with caution, in patients with abnormalities of the oesophagus or factors delaying oesophageal emptying. In the absence of robust comparative data, clinical experience suggests that risedronate may be preferable in patients with significant pre-existing upper GI problems (including oesophagitis, peptic ulcer, Barrett's oesophagus and active gastritis) and those who develop significant GI side-effects with alendronate. Risedronate may also be preferred in patients with glucocorticoid induced osteoporosis.

For further information go to [Section 6.6 of the TAPG](#)

Recommendation for suspension of sibutramine (Reductil®)

The marketing authorisations for the anti-obesity drug sibutramine have been recommended to be suspended across Europe. Evidence suggests that there is an increased risk of non-fatal heart attacks and strokes with this medicine that outweighs the benefits of weight loss, which is modest and may not be sustained in the long term after stopping treatment. Prescribers are advised not to issue new any new prescriptions for sibutramine and to review the treatment of patients taking the drug. Pharmacists should not dispense any prescriptions for sibutramine and should advise patients to make a routine appointment with their doctor to discuss alternative measures to lose weight. There are no health implications if patients wish to stop treatment before seeing their doctor.

For further information please see the [MHRA website](#).

Exenatide – Revision of the new medicine treatment protocol and local recommendation

Exenatide (Byetta®) protocol

Sections 3, 5 and 8 of this protocol have recently been modified following the introduction of liraglutide injection. A new section (**Section 11**) has been added which covers special storage requirements.

For further information, please [click here](#)

Section 3:

Medicines Advisory Group advice is now:
Third line anti-diabetic agent for glycaemic control
Non-formulary

Section 5: Criteria for patient selection now reads:
Exenatide can be considered as a third line agent in patients whose BMI is $>30 \text{ kg/m}^2$, in whom weight gain is a concern, and who do not have osmotic symptoms. Exenatide is not suitable for patients who clearly require insulin therapy. In rare cases of extreme obesity where the weight benefits are desirable, exenatide may be used in combination with metformin as dual therapy.

Section 8: The following sentence has been added:

In practice, when initiating exenatide, a 50 percent reduction in the dose of a sulphonylurea may be recommended and stepped up as necessary.

Section 11: Special storage precautions:

Store in a refrigerator (2°C - 8°C). Do not freeze.

In use: Store below 25°C.

The pen should not be stored with the needle attached. Replace cap on pen in order to protect from light.

Pegaptanib - Update

Following the NHS QIS validation of NICE MTA guidance, pegaptanib 0.3mg solution for intravitreal injection (Macugen®), for the treatment of Age Related Macular Degeneration (AMD), is not recommended for local use.

This recommendation supersedes previous [SMC advice](#).

Medicine	Indication	Local recommendation category	Comments and useful links
Bemiparin 3,500 IU in 0.2ml solution for injection in prefilled syringes (Zibor [®]) <i>2nd Re-submission</i>	Thromboembolic disease in patients undergoing orthopaedic surgery	Not recommended in Tayside Non formulary	SMC advice
Eslicarbazepine (Zebinix [®]) 800mg tablets <i>Full submission</i>	Adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation	Not recommended	SMC advice
Imatinib 100mg and 400mg film-coated tablets (Glivec [®]) <i>Full submission</i>	Adjuvant treatment of adult patients who are at significant risk of relapse following resection of Kit (CD117)-positive gastrointestinal stromal tumours (GIST)	Not recommended	SMC advice
Liraglutide 6mg/mL prefilled pen for injection (3mL) (Victoza [®]) <i>Full submission</i>	Restricted use as a third line agent for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control. <ul style="list-style-type: none"> in combination with metformin or a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin or sulphonylurea in combination with metformin and a sulphonylurea or metformin and a thiazolidinedione in patients with insufficient glycaemic control despite dual therapy. 	Non formulary Third line anti-diabetic agent for glycaemic control GPs may prescribe under the direction of the Diabetic Clinic	SMC advice SPC link New medicine treatment protocol Tayside Diabetes Handbook
Plerixafor (Mozobil [®]) 200mg/mL solution for injection <i>Full submission</i>	In combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma whose cells mobilise poorly	Pending OHMMG decision	SMC advice SPC link
Pramipexole dihydrochloride monohydrate prolonged release tablets 0.375mg, 0.75mg, 1.5mg, 3.0mg, 4.5mg (equivalent to 0.26mg, 0.52mg, 1.05mg, 2.1mg, 3.15mg pramipexole) (Mirapexin [®]) <i>Abbreviated submission</i>	Signs and symptoms of idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa i.e. over the course of the disease	Non formulary GPs may prescribe under the direction of specialist	SMC advice SPC link
Rituximab (MabThera [®]) 100mg and 500mg concentrate for solution for infusion <i>Full submission</i>	Previously untreated and relapsed/refractory chronic lymphocytic leukaemia (CLL) in combination with chemotherapy	Pending OHMMG decision	SMC advice SPC link
Tafuprost 15 micrograms/ml preservative-free eye drops single-dose container (Safutan [®]) <i>Full submission</i>	Restricted use for the reduction of elevated intraocular pressure in open angle glaucoma and ocular hypertension <ul style="list-style-type: none"> as monotherapy: in patients who would benefit from preservative-free eye-drops, who are insufficiently responsive to first-line therapy, or who are intolerant or contraindicated to first-line therapy or as adjunctive therapy to beta-blockers. 	Non formulary GPs may prescribe under the direction of the Eye Clinic	SMC advice SPC link <i>Restricted to use in patients who cannot tolerate currently available prostaglandin preparations due to proven sensitivity to the preservative benzalkonium chloride</i>

SMC Advice issued in December 2009 and January 2010 - continued

Medicine	Indication	Local recommendation category	Comments and useful links
Tocilizumab (RoActemra®) 200mg/mL concentrate for solution for injection <i>Full submission</i>	Moderate to severe active rheumatoid arthritis in adult patients Restricted for use in combination therapy within NHS Scotland	Pending specialist feedback	SMC advice SPC link
Tolvaptan 15mg tablet (Samsca®) <i>Non-submission</i>	Hyponatraemia secondary to syndrome of inappropriate antidiuretic hormone secretion (SIADH)	Not recommended	SMC advice
Valganciclovir powder for 50mg/ml oral solution (Valcyte®) <i>Abbreviated submission</i>	Induction and maintenance treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS)	Pending AMG decision	SMC advice SPC link
Valganciclovir powder for 50mg/ml oral solution (Valcyte®) <i>Abbreviated submission</i>	Restricted use for the prevention of CMV disease in CMV-negative patients who have received a solid organ transplant from a CMV-positive donor	HOSPITAL ONLY To be initiated by specialists experienced in the care of post-transplant patients	SMC advice SPC link <i>Restricted to patients unable to take the solid oral dosage form</i>

Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
11.7mg Etonogestrel/2.7mg ethinylestradiol vaginal ring (NuvaRing®) <i>Re-submission</i>	Contraception	Non-formulary	SMC advice SPC link
Fentanyl 50 micrograms/dose, 100 micrograms/dose, 200 micrograms/dose nasal spray (Instanyl®)	Restricted use for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain.	Non formulary Treatment should be initiated by and remain under the supervision of a physician experienced in the management of opioid therapy in cancer patients	SMC advice SPC link <i>Tayside Prescriber being produced on the use of short acting fentanyl preparations</i>
Rotigotine, 1mg, 2mg and 3mg per 24 hours transdermal patch (Neupro®)	Symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome (RLS) in adults.	GPs may prescribe under the direction of the Movement Disorders Clinic	SMC advice SPC link <i>Counsel patients to report any vision abnormalities to their GP or specialist. No other routine ophthalmic monitoring required</i>

SMC Briefing Notes:

Click here for [December](#) and [January](#) Briefing Notes

Tayside Area Prescribing Guide (TAPG) Updates – December 2009/January 2010

	TAPG section	Drug(s)/topic	Changes
Section 2	Cardiovascular System Guidelines	Management of Hypertension	Aspirin information removed and replaced with link to Tayside Prescriber Issue No 110 – Aspirin and primary prevention
		Prevention of Cardiovascular Disease	Link to Tayside Prescriber Issue No 110 inserted. Minor amendments to cardiovascular risk table. Note on aspirin and diabetes mellitus added.
Section 2.9	Antiplatelet drugs	Aspirin	Link to Tayside Prescriber Issue No 110 inserted. Dose information updated.
		Clopidogrel	Dose information minor amendment. Further information added to clarify indications, doses and durations of therapy.
Section 6.4	Sex Hormones	HRT	Link to Tayside Menopause Guidelines inserted. Removal of FemTab Sequi [®] tablets as discontinued.
Section 6.6	Drugs affecting bone metabolism	Bisphosphonates	Update to prescribing advice for alendronate and risedronate.
Sections 7.2 and 7.3	Treatment of vaginal and vulval disorders and Contraceptives	Vaginal atrophy	Dose information for estradiol vaginal tablets 25micrograms (Vagifem [®]) updated. Minor changes to prescribing notes on topical estrogens.
		Combined hormonal contraceptives	Layout of section updated. Addition of combined oral contraceptive (COC) Femodene [®] . Addition of combined contraceptive patch Evra [®] * for women who are at substantial risk of poor compliance with COCs.
		Progestogen-only contraceptives	Information on desogestrel 75micrograms tablets (Cerazette [®] *) expanded with recommendation as first choice progestogen-only oral preparation (POP) for less compliant women and in those with a history of ectopic pregnancy who take a POP. Norethisterone (Noriday [®] /Micronor [®]) or etynodiol (Femulen [®]) remain the first choice POP for the majority of patients. Etonogestrel implant (Implanon [®]) (long-acting reversible contraception) added as full entry.

Tayside Area Prescribing Guide (TAPG) Updates – December 2009/January 2010-cont'd

Section 7.4	Drugs for genito-urinary disorders	Alpha-blockers	Tamsulosin m/r capsules* now first choice alpha-blocker instead of doxazosin. Full entry for dutasteride* made. Link to MHRA Drug safety Update December 2009 for finasteride added due to reports of male breast cancer. Link to Tayside Urology Guidance - Lower Urinary Tract Symptoms added.
		Drugs for urinary frequency (in the absence of outflow obstruction)	Link to Tayside Urology Guidance - Urinary Incontinence added. Note added that higher unlicensed doses of oxybutynin - up to 30mg daily may be prescribed or recommended by specialists. Full entries added for solifenacin tablets* and tolterodine m/r capsules. Prescribing notes on antimuscarinic drugs amended.
		Drugs for erectile dysfunction	Link to Tayside Urology Guidance - Erectile Dysfunction added.
Section 8	Malignant disease and Immunosuppression	Prostate cancer	Layout of section updated. Prescribing notes on hormone therapy added. Bicalutamide added as first choice for single agent therapy. Cyproterone acetate to remain a first choice medicine but category now first choice to prevent tumour flare with gonadorelin therapy. Prescribing notes on cyproterone acetate added. Link to BNF inserted for further information on licensed indications of gonadorelin analogues.

* SMC accepted

Who produces this bulletin?

This bulletin is produced by the Medicines Advisory Group (MAG), which is a sub-group of the NHS Tayside Drug and Therapeutic Committee.

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Forthcoming SMC Advice

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