

## Tayside DTC Supplement No 57

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### SMC Advice Issued April 2006

#### **Cinacalcet (Mimpara<sup>®</sup>) – secondary hyperparathyroidism (SHPT)**

##### **SMC recommendation**

**Advice:** following a re-submission

Cinacalcet (Mimpara<sup>®</sup>) is not recommended for use within NHS Scotland for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy. Addition of cinacalcet to standard treatment with phosphate binders and/or vitamin D sterols reduced serum concentrations of parathyroid hormone and was associated with a reduced risk of fractures compared to standard treatment. However, the economic case was not demonstrated.

[Click here for SMC link](#)

##### **Tayside recommendation**

Not recommended

##### **Points for consideration:**

- Refer to [Tayside Prescriber: DTC Supplement No.50, May 2005](#) for original SMC advice.
- Whilst studies have shown that cinacalcet is effective in reducing serum concentrations of parathyroid hormone, there are concerns around the cost-effectiveness of treatment versus existing standard care ie phosphate binders (eg calcium, aluminium salts, and sevelamer) and vitamin D analogues (eg calcitriol and alfacalcidol).
- A NICE multiple technology appraisal of cinacalcet for the treatment of SHPT in patients with end stage renal disease on maintenance dialysis therapy is due for publication in December 2006.

#### **Daptomycin (Cubicin<sup>®</sup>) – complicated skin and soft tissue infections (cSSTIs) in adults**

##### **SMC recommendation**

**Advice:** following a full submission

Daptomycin (Cubicin<sup>®</sup>) is accepted for restricted use within NHS Scotland for the treatment of complicated skin and soft tissue infections in adults.

Daptomycin should be restricted to use in patients with known or suspected *methicillin-resistant Staphylococcus aureus* (MRSA) infection and on the advice of local microbiologists or specialists in infectious disease. Daptomycin has a higher acquisition cost than some alternative treatments; it does not, however, require therapeutic drug monitoring.

##### **Tayside recommendation**

Not currently recommended – pending ASD Anti-infectives policy decision

##### **Points for consideration:**

- Daptomycin is the first of a new class of antibacterials, the cyclic lipopeptides. It is active against Gram-positive bacteria including MRSA.

*Continued over*

#### *Daptomycin continued*

- Daptomycin has been shown to be as effective as vancomycin in patients with severe cSSTIs, proven MRSA infection, or MRSA risk factors. Of note, only a small proportion of patients within the key clinical studies (10%) had proven MRSA; this may affect the extrapolation of overall study results to MRSA infection in practice.
- There are no *in vivo* comparative data for daptomycin versus other IV antibiotics used in the treatment of MRSA skin infection eg linezolid, teicoplanin or quinupristin/dalfopristin (Synercid<sup>®</sup>).
- Daptomycin has been reported to have the potential for muscle toxicity. In clinical studies, elevated plasma creatine phosphokinase (CPK) levels were reported in 2% of daptomycin-treated patients. The SPC advises that plasma CPK should be measured at baseline and at regular intervals (at least once weekly) during therapy in all patients. Daptomycin should not be administered to patients who are taking other medicines associated with myopathy unless the benefits are considered to outweigh the risks.
- At £620 per 10 day course\*, daptomycin is nearly twice as expensive as vancomycin – the first-line IV treatment for MRSA skin and soft tissue infection currently recommended within the Tayside MRSA Policy. Unlike vancomycin, daptomycin does not require serum monitoring and has the advantage of once daily dosing.
- Refer to the [Hospital Adult Antibiotic Policy](#) within the [Tayside Area Prescribing Guide \(TAPG\)](#) for details of the local MRSA Policy.
- **The place of daptomycin in the local treatment of MRSA skin and soft tissue infection will be addressed by the ASD Anti-infectives Sub-Committee. Prescribers are advised to await the antibiotic policy decision.**

\* NHS list price excl. VAT

#### **Glyceryl Trinitrate 0.4% (Rectogesic<sup>®</sup>) – relief of pain associated with chronic anal fissure**

##### **SMC recommendation**

**Advice:** following a re-submission

Glyceryl Trinitrate rectal ointment (Rectogesic<sup>®</sup>) is not recommended for use within NHS Scotland for the relief of pain associated with chronic anal fissure.

It was associated with very small improvements in pain scores compared with vehicle. The economic case for this product was not demonstrated.

[Click here for SMC link](#)

##### **Tayside recommendation**

Not recommended

##### **Points for consideration:**

- Refer to [Tayside Prescriber, DTC Supplement No.54, December 2005](#) for original SMC advice.
- Unlicensed 0.2% glyceryl trinitrate (GTN) rectal ointment has been available for a number of years and is widely used for the treatment of chronic anal fissure.
- Unlike the unlicensed 0.2% formulation, there are no data to indicate the use of Rectogesic<sup>®</sup> is associated with improved healing of anal fissure.
- **Locally, 0.2% GTN rectal ointment (available from Tayside Pharmaceuticals) is used to heal chronic anal fissure.**
- Rectogesic<sup>®</sup> ointment is not stocked by the hospital pharmacy.

#### **Sodium Oxybate (Xyrem<sup>®</sup>) – cataplexy in adults with narcolepsy**

##### **SMC recommendation**

**Advice:** following a full submission

Sodium Oxybate (Xyrem<sup>®</sup>) is not recommended for use within NHS Scotland for the treatment of cataplexy in adult patients with narcolepsy.

In two studies the median percent decrease in weekly cataplexy attacks ranged from 49% to 85% for the dose range included in the product licence.

However, the economic case for this product was not demonstrated.

[Click here for SMC link](#)

*Continued over*

*Sodium oxybate continued*

### **Tayside recommendation**

Not recommended

### **Points for consideration:**

- Cataplexy is an abrupt, reversible decrease in muscle tone caused by emotion, such as laughter, elation or anger. It is reported in about 75% of patients with narcolepsy.
- Sodium oxybate is the sodium salt of gamma hydroxybutyrate (GHB) and is thought to act as a neurotransmitter in the regulation of sleep cycles, blood flow, emotion and memory.
- There are no comparative data for sodium oxybate versus alternative treatments used to control cataplexy ie tricyclic antidepressants, selective serotonin re-uptake inhibitors (SSRIs) and monoamine-oxidase inhibitors (MAOIs). Clomipramine is the only treatment licensed for use in cataplexy.
- Sodium oxybate is a schedule 4 (part 1 CD Benz) controlled drug in the UK.
- Sodium oxybate is not stocked by the hospital pharmacy.

## **Forthcoming SMC Advice**

<b>Gastro-intestinal system</b>
Esomeprazole (Nexium <sup>®</sup> )
Beclometasone Dipropionate 5mg (Clipper <sup>®</sup> )
Mesalazine (Asacol <sup>®</sup> )
<b>Cardiovascular system</b>
Perindopril (Coversyl <sup>®</sup> )
Nebivolol (Nebilet <sup>®</sup> )
Olmesartan (Olmotec Plus <sup>®</sup> ) - <i>Abbreviated</i>
Losartan/hydrochlorothiazide (Cozaar <sup>®</sup> -Comp)
<b>Respiratory</b>
Omalizumab (Xolair <sup>®</sup> )
Beclometasone inhaler (Clenil <sup>®</sup> Modulite <sup>®</sup> )
Ciclesonide (Alvesco <sup>®</sup> ) paed
<b>Central nervous system</b>
Escitalopram (Ciprallex <sup>®</sup> )
Ropinirole (Adartrel <sup>®</sup> )
Rivastigmine (Exelon <sup>®</sup> )
Pregabalin (Lyrica <sup>®</sup> ) – <i>IRP</i>
Pramipexole (Mirexapin <sup>®</sup> )
Fentanyl patch (Durogesic <sup>®</sup> D Trans)
Zonisamide (Zogegran <sup>®</sup> )
Topiramate (Topamax <sup>®</sup> )
Duloxetine (Cymbalta <sup>®</sup> )
<b>Infections</b>
Tigecycline (Tygacyl <sup>®</sup> )
Posaconazole (Noxafil <sup>®</sup> )
Interferon-α-2b/ribavirin (Viraferon/Rebetol <sup>®</sup> )
Ertapenem (Invanz <sup>®</sup> ) - <i>Abbreviated</i>
<b>Endocrine system</b>
Somatropin (Norditropin SimpleXx <sup>®</sup> ) - <i>Abbreviated</i>
Pioglitazone/metformin - <i>Abbreviated</i>

<b>Endocrine system (contd)</b>
Inhaled insulin (Exubera <sup>®</sup> )
Pegvisomant (Somavert <sup>®</sup> ) - <i>Resubmission</i>
Testosterone (Testim <sup>®</sup> ) - <i>Abbreviated</i>
Rosiglitazone/metformin (Avandamet <sup>®</sup> ) - <i>Abbreviated</i>
Insulin glulisine (Apidra <sup>®</sup> )
Desmopressin (Desmomelt <sup>®</sup> ) - <i>Abbreviated</i>
<b>Obstetrics, Gynaecology and UTD</b>
Dinoprostone (Propess <sup>®</sup> ) - <i>Abbreviated</i>
<b>Malignant disease &amp; immunosuppression</b>
Lanreotide (Somatuline <sup>®</sup> LA)
Mitotane (Lysodren <sup>®</sup> )
Letrozole (Femara <sup>®</sup> )
Fludarabine (Fludara <sup>®</sup> Oral)
Sunitinib (Sutent <sup>®</sup> )
Bevacizumab (Avastin <sup>®</sup> ) - <i>Resubmission</i>
Erlotinib (Tarceva <sup>®</sup> ) - <i>Resubmission</i>
Trastuzumab (Herceptin <sup>®</sup> )
Cetuximab (Erbix <sup>®</sup> )
<b>Nutrition &amp; Blood</b>
Darbepoetin alfa (Aranesp <sup>®</sup> )
Lanthanum carbonate (Fosrenol <sup>®</sup> )
Paricalcitol (Zemlar <sup>®</sup> )
Cinacalcet (Mimpara <sup>®</sup> ) - <i>Resubmission</i>
<b>Musculoskeletal and joint diseases</b>
Etoricoxib (Arcoxia <sup>®</sup> ) - <i>Abbreviated</i>
Etanercept (Enbrel <sup>®</sup> ) - <i>Abbreviated</i>
<b>Eye</b>
Dorzolamide (Trusopt <sup>®</sup> )
Pegaptanib sodium (Macugen <sup>®</sup> )
<b>Skin</b>
Clobetasol propionate (Clarelux <sup>®</sup> ) - <i>Abbreviated</i>

**Contact details:** Local implementation of SMC recommendations is being taken forward by the Tayside Medicines Unit – contact Jan Jones, Pharmaceutical Prescribing Adviser ([jan.jones@tpct.scot.nhs.uk](mailto:jan.jones@tpct.scot.nhs.uk)) if you have any queries in relation to the introduction of new drugs within NHS Tayside

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