

# TAYSIDE PRESCRIBER

## Tayside DTC Supplement No 75

Dec 2007

Produced by NHS Tayside Drug and Therapeutics Committee

### SMC Advice issued in December 2007

| Medicine  | Indication  | Local recommendation category   | Comments and useful links   |
|---|---|---|---|
| Bevacizumab (Avastin <sup>®</sup> )<br><i>Non-submission</i>                                  | Advanced non-small cell lung cancer (NSCLC)   | Not recommended   | <a href="#">SMC Advice</a>  |
| Eculizumab (Soliris <sup>®</sup> )<br><i>Non-submission</i>                                   | Paroxysmal nocturnal haemoglobinuria (PNH)  | Not recommended   | <a href="#">SMC Advice</a>  |
| Esomeprazole (Nexium <sup>®</sup> )   | Zollinger-Ellison Syndrome  | May be prescribed under the direction of the GI clinic  | Restricted to patients unresponsive to max. licensed doses of other PPIs<br><a href="#">SMC Advice</a><br><a href="#">SPC link</a>                                      |
| Fondaparinux (Arixtra <sup>®</sup> )  | Unstable angina or non-ST segment elevation myocardial infarction (NSTEMI)                                  | Pending SMC advice for use in STEMI   | <a href="#">SMC Advice</a><br><a href="#">CCU Therapeutic Schedule</a><br><a href="#">Policy Guidelines</a>   |
| Fosamprenavir (Telzir <sup>®</sup> )<br><i>Non-submission</i>                                 | Human immunodeficiency Virus Type 1 (HIV-1) in children over 6 years  | Not recommended   | NB fosamprenavir is accepted for use in adults<br><a href="#">SMC Advice</a>  |
| Imatinib (Glivec <sup>®</sup> )<br><i>Non-submission</i>                                      | Myelodysplastic/myeloproliferative diseases (MDS/MPD)   | Not recommended   | <a href="#">SMC Advice</a>  |
| Imatinib (Glivec <sup>®</sup> )<br><i>Non-submission</i>                                      | Combination therapy in newly diagnosed Philadelphia chromosome +ve acute lymphoblastic leukaemia (PH + ALL) | Not recommended   | <a href="#">SMC Advice</a>  |
| Imatinib (Glivec <sup>®</sup> )<br><i>Non-submission</i>                                      | Monotherapy in relapsed/refractory PH+ ALL  | Not recommended   | <a href="#">SMC Advice</a>  |
| Imatinib (Glivec <sup>®</sup> )<br><i>Non-submission</i>                                      | Dermatofibrosarcoma protuberans (DFSP)  | Not recommended   | <a href="#">SMC Advice</a>  |
| Imatinib (Glivec <sup>®</sup> )<br><i>Non-submission</i>                                      | Advanced hypereosinophilic syndrome (HES), chronic eosinophilic leukaemia (CEL)                             | Not recommended   | <a href="#">SMC Advice</a>  |
| Risedronate (Actonel <sup>®</sup> )<br><i>Non-submission</i>                                  | Osteoporosis <u>in men</u>  | Not recommended   | <a href="#">SMC Advice</a>  |
| Rivastigmine transdermal patch (Exelon <sup>®</sup> )<br><i>Abbreviated submission</i>        | Moderately severe Alzheimer's dementia  | May be prescribed according to the cholinesterase inhibitor shared care protocol (under revision) | Alternative to tablets in patients who require once daily administration or have swallowing difficulties<br><a href="#">SMC Advice</a><br><a href="#">SPC link</a>      |
| Sevelamer (Renagel <sup>®</sup> )   | Hyperphosphataemia in adult patients receiving <u>peritoneal dialysis</u>                                   | Not recommended   | NB treatment should not be discontinued in existing patients<br><a href="#">SMC Advice</a>  |
| Tiotropium respimat inhaler (Spiriva-Respimat <sup>®</sup> )<br><i>Abbreviated submission</i> | COPD  | Formulary   | NB two 2.5mcg puffs from Respimat = one 18mcg blister from Handihaler<br><a href="#">SMC Advice</a><br><a href="#">SPC link</a><br><a href="#">TAPG COPD guidelines</a> |
| Topotecan (Hycamtin <sup>®</sup> )  | Combination therapy in carcinoma of the cervix  | Not recommended   | <a href="#">SMC Advice</a>  |

## Strontium ranelate update

Further to the availability of open-access DXA scanning in parts of Tayside, February 06 local advice for the use of strontium ranelate for the treatment of postmenopausal osteoporosis has been updated to allow GPs to initiate treatment in women over 75 years with a previous fragility fracture and a T-score of < -2.4 in whom bisphosphonates are contraindicated or not tolerated.

Note recent safety advice on the risk of severe hypersensitivity reactions associated with strontium ranelate. [Click here](#) for further information.

## Omalizumab update

Further to the development of a local protocol, NHS Tayside advice for the use of omalizumab in severe allergic asthma has been updated as follows:

### Tayside recommendation

HOSPITAL ONLY (Chest or Rhinology Clinics)

- Omalizumab is restricted to patients with objective evidence of refractory persistent severe allergic asthma (baseline IgE <700IU/ml) not controlled on optimised BTS step 5 therapy – who have adequately implemented allergen avoidance measures and where other relevant trigger factors have been addressed such as concomitant allergic rhinosinusitis, smoking, occupation, GERD.
- The local protocol will be posted on the DTC website shortly.

## TAPG Update

|    | TAPG section                | Drug(s)/topic    | Changes  |
|----|-----------------------------|------------------|--|
| 1  | Gastro-intestinal system    | Esomeprazole*    | Addition to approved use – may be prescribed under the direction of the GI clinic for those with Zollinger-Ellison Syndrome unresponsive to maximum licensed doses of other PPIs.                            |
| 3  | Respiratory                 | Tiotropium*      | Aerosol inhaler (Respimat®) added.   |
|    |                             | Inhaled steroids | Seretide® – statement on dose increase during exacerbations removed in line with recent <a href="#">SIGN/BTS update</a> .  |
| 4  | Pain Guidance               | Neuropathic pain | Further advice inserted on dose titration of amitriptyline and gabapentin. Also links to Tayside patient information leaflets for both drugs.  |
| 6  | Endocrine                   | Bisphosphonates  | Advice on preferred use of risedronate to alendronate in certain patient groups. Advice on risk of osteonecrosis of the jaw associated with bisphosphonates. See <a href="#">Drug Safety Update Oct 2007</a> |
|    |                             | Glitazones       | Advice on glitazone use in patients with established cardiac disease.  |
| 18 | Therapeutic drug monitoring | Reporting units  | Change of units for reporting drug and poison concentrations. Refer to <a href="#">Biochemical Medicine Bulletin</a> for further info.   |

\* SMC accepted medicine

## Advice on glitazone use in patients with established cardiac disease

The European Medicines Agency (EMA) has recently reviewed information regarding the risks and benefits of both rosiglitazone and pioglitazone, as part of its continuing monitoring of medicines. Further information is available in their [press release \(18-10-2007\)](#) and within a [Q&A document](#). A summary of this advice is provided in the box below:

- The benefits of both rosiglitazone and pioglitazone continue to outweigh their risks.
- Rosiglitazone seems to be associated with an increased risk of ischaemic heart disease, but this does not seem to be associated with an increased risk of death. However further studies examining this are required.
- Rosiglitazone should only be used in patients with ischaemic heart disease after careful evaluation of each patient's individual risk.
- The prescribing information for rosiglitazone will be updated to include this warning.
- No changes to the prescribing information for medicines containing pioglitazone were considered necessary.

### Note

- The Proactive study published in 2005 suggests a modest beneficial effect of pioglitazone in patients who are at high risk of cardiovascular events, and this study included patients with previous MI.
- Cardiac failure remains a contraindication to the use of both drugs.
- Further information is available within the December issue of [Drug Safety Update](#).

*Tayside Diabetes Network, Nov 2007*

## Forthcoming SMC Advice

**Contact details:** Local implementation of SMC recommendations is taken forward by the Tayside Medicines Unit - contact Jan Jones, Principal Pharmacist - Pharmacoeconomics ([janjones@nhs.net](mailto:janjones@nhs.net)) if you have any queries in relation to the introduction of new drugs within NHS Tayside.

This bulletin is based on evidence available to the Tayside Medicines Unit at time of publication and is covered by the Disclaimer and Terms & Conditions of use and access to the NHS Tayside Drug and Therapeutics Committee website ([www.nhstaysideadtc.scot.nhs.uk](http://www.nhstaysideadtc.scot.nhs.uk)).