

Tayside D&TC Supplement No. 25

April 2003

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Escitalopram (Cipralex[®]) – depression

➤ Recommended for use

- Further to a resubmission by the manufacturer, the SMC has revised their original escitalopram advice issued in November 2002 (refer to Tayside D&TC Supplement Issue No. 22).

Points for local consideration:

- Escitalopram has been shown to be as effective as citalopram in short-term use.
- A health economic model submitted to the SMC suggests that escitalopram is also as cost-effective as citalopram. However the resource usage assumptions and clinical evidence underpinning the model are not robust and no clear benefits are demonstrated over the parent product – citalopram, or other effective and cheaper agents.
- Fluoxetine is currently the most cost-effective Selective Serotonin Re-uptake Inhibitor (SSRI)
- Fluoxetine and paroxetine are recommended in the Tayside Area Prescribing Guide (TAPG) as the SSRIs of choice locally.

Etoricoxib (Arcoxia[®]) – osteoarthritis (OA), rheumatoid arthritis (RA), acute gouty arthritis

- **Recommended for use** in accordance with guidelines issued by NICE for COX-2 selective NSAIDs in the treatment of OA and RA.
- Etoricoxib is a further COX-2 selective Non-Steroidal Anti-Inflammatory Drug (NSAID).

Points for local consideration

- Etoricoxib is effective in the symptomatic treatment of OA and RA, it is also effective in the treatment of acute gouty arthritis.
- In common with other COX-2 selective NSAIDs, etoricoxib is associated with less gastro-intestinal adverse-effects than non-selective NSAIDs and, therefore, should be reserved for patients at high risk of gastro-intestinal adverse-effects to non-selective NSAIDs.
- The risk of cardiovascular events in patients receiving COX-2 selective NSAIDs is unclear and may be higher than shown with standard NSAIDs. Furthermore, in patients who take low dose aspirin for cardiovascular protection, the benefit of COX-2 selective agents (to decrease gastrointestinal toxicity) is reduced.
- COX-2 selective NSAIDs have a similar rate of renal adverse events to standard NSAIDs.
- There is no evidence that etoricoxib has advantages or disadvantages compared with other COX-2 selective NSAIDs.
- Further advice on the management of patients with OA is available within the TAPG.

Yasmin[®] (drospirenone/ethinylestradiol) – combined oral contraceptive (COC)

➤ **Not recommended**

- Yasmin is a novel COC containing a standard dose of ethinylestradiol and a new progestogen, drospirenone which has mild anti-mineralocorticoid effects.

Points for local consideration

- There is no evidence that Yasmin has superior effects on acne, pre-menstrual symptoms or well-being compared to other standard strength COCs.
- Yasmin has shown a statistically significant favourable weight change of 0.3–0.7 kg compared to a standard strength COC over a period of 26 cycles. However, there is no evidence that patients who discontinue other COCs because of weight gain tolerate Yasmin any better.
- Yasmin is substantially more expensive than competitor products and provides little additional benefit for this additional cost.
- Yasmin is not stocked by the hospital pharmacy.

The following recommendations relate to HOSPITAL ONLY medicines

Capecitabine (Xeloda[®]) – locally advanced/metastatic breast cancer

> Restricted use

- Capecitabine is an oral prodrug of 5-fluorouracil. It is licensed to treat locally advanced/metastatic breast cancer in combination with docetaxel, after failure of cytotoxic chemotherapy (including an anthracycline), or as monotherapy after failure of taxanes and an anthracycline containing chemotherapy regimen.

Points for local consideration

- Capecitabine is an orally active treatment which has improved outcomes both as monotherapy in those previously treated with an anthracycline and a taxane, and in combination with docetaxel in those previously treated with an anthracycline.
- **Capecitabine is restricted to secondary care** and is recommended for use by oncologists with appropriate expertise in treating locally advanced/metastatic breast cancer.

Caspofungin - invasive aspergillosis

> Restricted use*

- Caspofungin is an antifungal agent licensed for the treatment of invasive aspergillosis in adults who are refractory to or intolerant of standard antifungal therapy.

Points for local consideration

- Efficacy and safety data to support the benefits of caspofungin in the treatment of invasive aspergillosis are extremely limited, in the form of one small, open-label, uncontrolled study.
- **Caspofungin is restricted to secondary care** as a salvage treatment in patients unresponsive or intolerant of amphotericin B, itraconazole and voriconazole on the recommendation of a consultant in Infectious Diseases.
- Further guidance on serious fungal infections is currently under development by the TUH Anti-infectives Sub-Committee.

*local adaptation of SMC advice

Rituximab (MabThera[®]) – non-Hodgkin's lymphoma

> Restricted use

- Rituximab is a monoclonal antibody which causes lysis of B lymphocytes. Its licence has been extended to include treatment of patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma in combination with CHOP chemotherapy (R-CHOP).

Points for local consideration

- **Rituximab is restricted to secondary care** for use by oncologists or haematologists who have expertise in treating lymphoma.

Bosentan (Tracleer[®]) – pulmonary arterial hypertension

➤ Restricted use

- Bosentan is a dual endothelin receptor antagonist licensed for the treatment of pulmonary arterial hypertension (PAH) to improve exercise capacity and symptoms in patients with grade III functional status.

Points for local consideration

- **Bosentan is restricted to the specialist pulmonary arterial hypertension centre.**
- Evidence of the efficacy and effectiveness of bosentan is limited. It offers major advantages over epoprostenol in ease of administration.
- Hepatotoxicity and teratogenicity concerns have led the EMEA to recommend a post-marketing programme.
- Bosentan is not stocked by the hospital pharmacy.

Esomeprazole – revised DEP recommendation

Esomeprazole was evaluated by the Drug Evaluation Panel (DEP) in December 2000. Further to a resubmission by local gastroenterologists, the original DEP recommendation has been revised as follows:

- Recommended under the direction of a gastroenterologist for the treatment of endoscopically proven grades c and d oesophagitis unresponsive to licensed treatment doses of other Proton Pump Inhibitors (PPIs).
- Further advice on the treatment of oesophagitis is currently being prepared by the GI formulary sub-group.
- Omeprazole and lansoprazole are recommended in the TAPG as the PPIs of choice locally.
- Omeprazole is available in a generic form, a favourable cost differential between omeprazole and other PPIs is anticipated.
- NICE recommends that the lowest dose of PPI that provides effective symptom relief should be used.

New medicines should not normally be prescribed until a recommendation for use has been issued by the SMC and this has been considered locally.

Details of local recommendations for new medicines are available on the Tayside D&TC web-site (www.show.scot.nhs.uk/thb/adtc). Information on which new medicines will be considered by the SMC over the next two to three months is available on the SMC web-site (www.scottishmedicines.org.uk) under “Work Programme”.

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) if you have any queries in relation to the introduction of new drugs within NHS Tayside

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