Tablet Press

The prescribing newsletter for GPs, nurses and pharmacists in Northamptonshire Primary Care Trust

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- **European Medicines Agency (EMA) finalises its review on pioglitazone**

The EMA's Committee for Medicinal Products for Human Use (CHMP) has finalised its review of pioglitazone following publication of data which suggested that use of the drug may be associated with an increased risk of bladder cancer. The CHMP confirmed that pioglitazone remain a valid treatment option for certain patients with type 2 diabetes but that there is a small increased risk of bladder cancer in patients taking these medicines. However, the CHMP also concluded that the small increased risk could be reduced by appropriate patient selection and exclusion, including a requirement for periodic review of the efficacy and safety of the individual patient's treatment.

The CHMP has advised prescribers:

- Not to use pioglitazone in patients with current or a history of bladder cancer or in patients with uninvestigated macroscopic haematuria.
- To assess risk factors for bladder cancer before initiating treatment with pioglitazone
- In light of age-related risks, to consider the balance of benefits and risks carefully both before initiating and during treatment in the elderly.
- They should review the treatment of patients on pioglitazone after three to six months (and regularly afterwards) to ensure that only patients who are deriving sufficient benefit continue to take it.

The CHMP concluded that there are some patients who cannot be adequately treated by other treatments and who will benefit from treatment with pioglitazone. The CHMP agreed that it was not possible to further restrict the current indications of pioglitazone. Instead, prescribers are advised to carefully select patients and monitor response to treatment. In patients responding to treatment, the CHMP concluded that the benefits outweigh the risks.
As there are still some unanswered questions, the CHMP has asked the marketing authorisation holder to conduct a pan-European epidemiological study focusing on more robust characterisation of the risk, in particular the risk period and risk with increasing age, to inform the evidence-base for risk minimisation measures.

- **Ranitidine liquid formulations:**

Ranitidine is available in two licensed liquid formulations, both the same strength but one is described as 150mg in 10ml ("Zantac syrup"), £20.76 for 300ml, the other is ranitidine oral solution sugar-free 75mg in 5ml, £19.30 for 300ml. Both these are now on the PCT formulary. If a practice is using its own formulary, it is recommended that these preparations are added.
The EMIS "drug dictionary" has recently added another UNLICENSED ranitidine preparation "Ranitidine Oral Suspension 5mg in 5ml". This is written in yellow and the prescribing note emphasises that this is an unlicensed medicine. However, it has been prescribed and/or dispensed on several occasions recently, resulting in 2 dispensing errors, with the administration to babies of 15 times the prescribed dose of ranitidine. In addition to the possibility of confusion of strengths and harm to patients, the prescribing of the unlicensed special costs between £212 - £708 for 200ml, depending on the supplier used.

- **Nutritional Supplements and Scriptswitch**

The dieticians within the Prescribing Advisory Team have recently reviewed nutritional supplements in view of new products emerging from the market. We are now advocating the use of 125mls Fortisip Compact as the milkshake supplement of choice when the patient's condition meets prescribing criteria.
To support you with this change Scriptswitch will be updated over the next few weeks to highlight which products are suitable to switch eg. Fortisip, Ensure Plus, Fresubin High Energy and Resource Energy.
Additionally, any queries can be directed to: Monica Compton on 01536 492320 or Karen Osborne on 01604 745036.

- **Risks of anticholinergic drugs on cognitive decline and mortality examined**

Further to the Tablet Press Extra regarding this recent observational study, the NPC have now done a MeReC Rapid Review which can be found at http://www.npc.nhs.uk/rapidreview/?p=4042
They conclude, "Although this study's findings broadly support the existing work evaluating anticholinergic exposure and cognitive impairment, the study has significant shortcomings which limit its interpretation and application to clinical practice". Patients should be advised not to stop any anticholinergic medication without a careful review of their treatment with their prescriber. A number of medicines have anticholinergic effects - in elderly patients, or those at increased risk of cognitive decline who are using multiple medications which have anticholinergic activity, their continued use should be balanced against their risks.

This edition is also available on HNN (Health Network Northants)
http://nww.northants.nhs.uk/Display/Dynamic.jsp?topid=14070&lhsid=514&oid=2854&currentid=2854