Tablet Press

The prescribing newsletter for GPs, nurses and pharmacists
NHS Nene CCG and NHS Corby CCG

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- **MHRA - New advice for domperidone**

The MHRA have now issued guidance following the new recommendations from the EMA's Pharmacovigilance Risk Assessment Committee (PRAC). These cover restricted indication, new contraindications, and reduced dose and duration of use based on the risk of cardiac side-effects.
https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102155

- **European Medicines Agency review of testosterone-containing medicines started**

The EMA has started a review of testosterone-containing medicines, mainly used in men who do not produce enough testosterone.
The review was triggered by the Estonian medicines agency over concerns about side effects of medicines containing testosterone on the heart. The safety concerns were raised following the recent publication of a study suggesting that the use of testosterone increases the risk of myocardial infarction in men aged over 65 years, as well as in younger men with pre-existing heart disease. This study follows other studies including the Veterans Health Care Study, which suggests that men with pre-existing heart disease who received treatment with testosterone had a higher risk of heart problems than men who did not receive testosterone.
The EMA will now review all available data on the benefit-risk balance of testosterone-containing medicines and issue an opinion on whether their marketing authorisations should be maintained, varied, suspended or withdrawn across the EU.
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/04/WC500165222.pdf

- **PRAC recommends against combined use of drugs affecting the renin-angiotensin system**

The PRAC has reviewed the risks of combining angiotensin-receptor blockers (ARBs/sartans), angiotensin-converting enzyme inhibitors (ACE-inhibitors) and direct renin inhibitors such as aliskiren. The PRAC has advised that combining drugs from any two of these classes should not be recommended, and in particular that patients with diabetic nephropathy should not be given an ARB with an ACE-inhibitor. Where such combination is considered absolutely necessary, it must be carried out under specialist supervision with close monitoring of kidney function, fluid and salt balance and blood pressure. (This would include the licensed use of the ARBs candesartan or valsartan as add-on therapy to ACE-inhibitors in patients with heart failure who require such a combination.) The combination of aliskiren with an ARB or ACE-inhibitor is strictly contraindicated in those with kidney impairment or diabetes.
The PRAC recommendation will now be forwarded to the Committee for Medicinal Products for Human Use (CHMP) which will adopt the Agency's final opinion.

- **Cilest – short expiry date**

We have been made aware that Cilest tablets have a maximum expiry date of 12 months; prescribers are therefore asked not to issue prescriptions for more than 6 months' supply at any one time in order to ensure that the packs dispensed will remain within their expiry date.

- **Incretin treatment and risk of pancreatitis in patients with type 2 diabetes**

Glucagon-like peptide-1 (GLP-1) receptor agonists and dipeptidyl peptidase-4 (DPP-4) inhibitors are two classes of incretin based treatments for type 2 diabetes.
A systematic review and meta-analysis published in the BMJ has concluded that "the available evidence suggests that the incidence of pancreatitis among patients using incretins is low and that the drugs do not increase the risk of pancreatitis. Current evidence, however, is not definitive and more carefully designed and conducted observational studies are warranted to definitively establish the extent, if any, of increased risk". http://www.bmj.com/content/348/bmj.g2366

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and on the Nene CCG and Corby CCG websites