Tablet Press

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

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- **Strontium ranelate (Protelos): risk of serious cardiac disorders**

A review of available safety data for strontium ranelate has raised concern about its CV safety beyond the already recognised risk of VTE. An analysis of RCT data has identified an increased risk of serious cardiac disorders, including MI. The EMA will fully evaluate the benefits and risks in the coming months. In the meantime, the MHRA advice is:

- Use of strontium is now restricted to treatment of severe osteoporosis
  - in postmenopausal women at high risk of fracture
  - in men at increased risk of fracture
- Treatment should only be initiated by a physician with experience in the treatment of osteoporosis, and the decision to prescribe strontium should be based on an assessment of the individual patient's overall risks
- Strontium should not be used in patients with: ischaemic heart disease, peripheral arterial disease; cerebrovascular disease; a history of these conditions; or in patients with uncontrolled hypertension
- Prescribers are advised to assess the patient's risk of developing cardiovascular disease before starting treatment and thereafter at regular intervals
- Patients with significant risk factors for cardiovascular events (eg, hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with strontium after careful consideration
- Treatment should be stopped if the patient develops ischaemic heart disease, peripheral arterial disease, cerebrovascular disease, or if hypertension is uncontrolled
- Healthcare professionals should review patients at a routine appointment
  http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON266148

- **Denosumab**

Denosumab is available as 2 different products and it has different traffic light status depending on the product and the indication. For osteoporosis it is amber – the product is Prolia. For bone metastases from solid tumours it is red – the product is Xgeva. See http://nww.pathfinder-rf.northants.nhs.uk/nene/therapeutics/traffic-light-drugs/

- **Tiotropium Respimat – another study finds increased mortality compared to Handihaler**

Tiotropium, a long-acting anticholinergic, is delivered via HandiHaler or Respimat. Previous RCTs already demonstrate that use of Tiotropium Respimat increases the risk of dying. An observational study published in the European Respiratory Journal http://www.ncbi.nlm.nih.gov/pubmed/23520322 compared the risk of mortality between tiotropium Respimat® vs. HandiHaler®.

Within the Integrated Primary Care Information database, a source population of patients, ≥40 years, with at least 1 year of follow-up was defined. Based on prescription data, episodes of tiotropium use (Respimat® or Handihaler®) were identified.

From the source population, 11287 patients provided 24522 episodes of tiotropium use. 496 patients died while being exposed to Handihaler® or Respimat®. Use of Respimat® was associated with almost 30% increased risk of dying (HRadj 1.27, 95% CI 1.03–1.57) with the highest risk for CV death (HRadj 1.56, 95% CI 1.08–2.25). The risk was higher in patients with co-existing cardiovascular disease (HRadj 1.36, 95% CI 1.07–1.73) than in patients without (HRadj 1.02, 95% CI 0.61–1.71).

Use of tiotropium Respimat® was associated with an almost 30% increase of mortality compared to Handihaler® and the association was the strongest for cardiovascular/cerebrovascular death. The authors note that is unclear whether this association is causal or due to residual confounding by COPD severity.

- **CareSens remains BGTS formulary choice**

We are aware that there is currently considerable manufacturer promotion of alternative blood glucose testing strips. However, CareSens remains the formulary choice in NHS Nene CCG and NHS Corby CCG.

- **"Green Book" Update**

The "Storage, distribution and disposal of vaccines" chapter in the Green Book (Immunisation against infectious disease) has been updated. As this chapter is very comprehensive it is recommended that everybody involved in vaccination reads it. Our local "cold chain policy" has been withdrawn.

The Green Book became the responsibility of Public Health England from 1st April. The new website address is: https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book

As the hard copy of the Green Book was last published in 2006 it is recommended that staff involved in vaccination e.g. childhood immunisation programme, travel, occupational health etc should use the website from now on.

This edition is also available on PathfinderRF via the following link http://nww.pathfinder-rf.northants.nhs.uk/nene
and on the Nene CCG and Corby CCG websites