North of England Commissioning Support Unit

Medicines Optimisation

Prescribing Memo

Strontium Ranelate (Proleos) Safety Concerns

Date: 1st May 2013 **Memo Number: 07/13**

A review of available safety data for strontium ranelate (Protelos) has raised concern about its cardiovascular safety beyond the already recognised risk of venous thromboembolism. An analysis of randomised controlled trial data has identified an increased risk of serious cardiac disorders, including myocardial infarction (relative risk compared with placebo was 1.6 [95% CI 1.07–2.38]).

The European Medicines Agency will fully evaluate the benefits and risks of strontium ranelate in the coming months. In the meantime, in order to help minimise these risks the following is recommended:

Advice for healthcare professionals from the MHRA:

- Use of strontium ranelate 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 ranelate should be based on an assessment of the individual patient's overall risks
- Strontium ranelate 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 ranelate 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 and consider whether or not to continue treatment
- Suspected adverse reactions to strontium ranelate should be reported to the MHRA on a Yellow Card.

Further information can be found on the EMA website in their press release of 26th April 2013. This can be found at www.ema.europa.eu

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For further information please check the Medicines Management website
www.cddmedicinesmanagement.nhs.uk,
email cd-pct.medicines@nhs.net, or telephone 0191 374 4121.