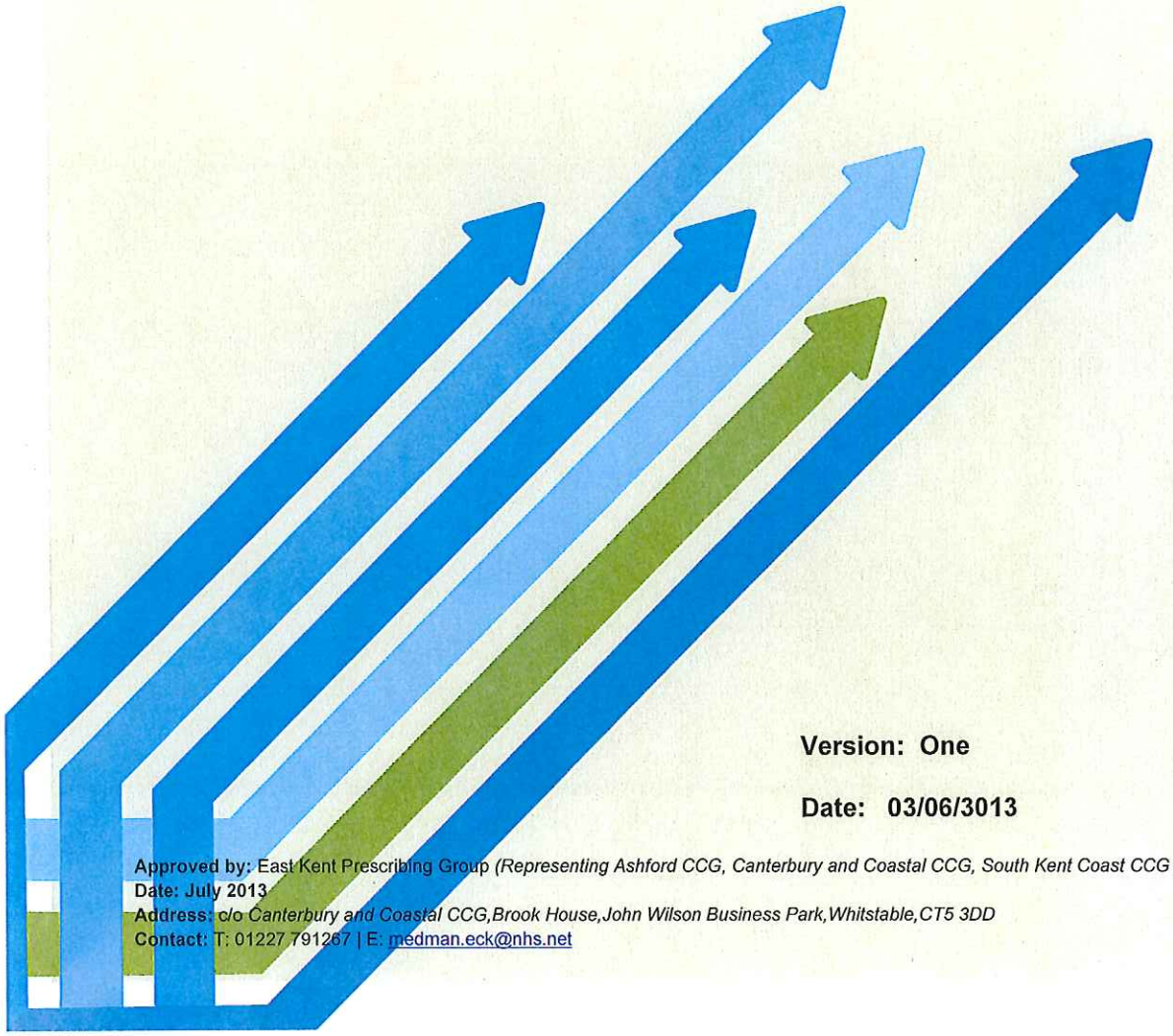
KMCS

Kent and Medway
Commissioning Support Unit

Kent and Medway Osteoporosis Group

Guidance for Strontium Ranelate



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Date: July 2013
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Executive Summary:

At the May, 2013 meeting of the Kent and Medway Osteoporosis Group, the recent MHRA alert was discussed. The MHRA have issued a warning concerning the review of available safety data for Strontium Ranelate and the cardiovascular risks beyond the already recognised risks of venous thromboembolism.

The Kent and Medway Osteoporosis Group have agreed a statement offering a recommendation on the use of Strontium Ranelate. The Kent and Medway Osteoporosis Group is chaired by Dr. Paul Ryan and includes General Practitioners in its membership, alongside secondary care clinicians specialising in the management of patients with osteoporosis.

It is requested that this paper, offering a recommendation on the use of Strontium Ranelate, is considered through the appropriate CCG decision making groups and the response is directed back to the Kent and Medway Osteoporosis Group for information and clarification.

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Kent and Medway Osteoporosis Group (KMOG) Guidance on Strontium Ranelate:

As you may be aware, recent analysis of studies using Strontium Ranelate has identified a statistically small increase risk of non fatal myocardial infarction. The mechanism by which this could occur is unknown. In light of the MHRA statement, and concerns identified regarding myocardial infarction, KMOG advises Strontium Ranelate should only be initiated in the future by secondary care osteoporosis specialists or other doctors with a special interest in osteoporosis and who regularly manage such patients.

All patients with a medical history placing them at risk i.e. ischaemic heart disease, peripheral arterial disease, cerebrovascular disease, uncontrolled hypertension, should stop treatment. Those with significant risk factors for cardiovascular disease should probably stop treatment but the relative risks of Myocardial Infarct versus osteoporotic fracture and their sequelae will need to be considered.

For patients under osteoporosis specialists at present, and due to be seen within the next 3 months, stop treatment if there is concern and alternatives can be considered at the next visit. For others, consider using a bisphosphonate. If this is not possible then refer to your appropriate osteoporosis specialist for advice. It may be possible to advise by letter but we recognise some will need to be seen in clinic.

Ref:- MHRA Alert . *Drug Safety Update April 2013 vol 6, issue 9:S1*

Strontium ranelate (Protelos): risk of serious cardiac disorders—restricted indications, new contraindications, and warnings

Article date: April 2013

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, updated advice is available:

Advice for healthcare professionals:

- 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 (e.g., 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