

Memo – discontinuation of supply

Date: June 2017

Re: Protelos (strontium ranelate) 2g granules for oral suspension

Description of product affected

Strontium ranelate is licensed for the treatment of severe osteoporosis in postmenopausal women and in adult men, at high risk of fracture, for whom treatment with other medicinal products approved for the treatment of osteoporosis is not possible due to, for example, contraindications or intolerance.¹

NICE recommends use of strontium ranelate as an alternative treatment option for the primary and secondary prevention of osteoporotic fragility fractures in postmenopausal women who are unable to comply with the special instructions for the administration of alendronate and either risedronate or etidronate, or have a contraindication to or are intolerant of these agents, and who also have a combination of T-score, age and number of independent clinical risk factors for fracture.^{2,3}

Restricted indication and new monitoring requirements were brought in for strontium ranelate in March 2014 following a review by the European Medicines Agency of the risks and benefits of treatment. The Agency recommended against starting treatment in people who have or have had: ischaemic heart disease/peripheral arterial disease/cerebrovascular disease/ uncontrolled hypertension.⁴

Background

Servier will cease production and distribution of strontium ranelate at the end of August 2017. This worldwide and strategic decision has been taken for commercial reasons due to the restricted indication/limited use of strontium ranelate, and the continuous decrease in the number of patients being treated with it.⁵

Alternative agents and management options

Therapies used in the management of osteoporosis are designed to reduce the risk of fracture. They work by either reducing the rate of bone turnover (antiresorptives) or stimulating bone formation (anabolic therapies). Antiresorptive therapies include bisphosphonates, raloxifene, HRT and denosumab. Parathyroid hormones, such as teriparatide, have a purely anabolic or bone-forming action (strontium ranelate has a dual role as antiresorptive and some bone-forming activity).⁶

In addition to bisphosphonates and strontium ranelate, NICE guidance on the secondary prevention of osteoporotic fragility fractures in postmenopausal women also supported the use of raloxifene³, teriparatide³ and denosumab⁷ in specific situations. In the primary prevention setting, NICE supports use of bisphosphonates² and denosumab⁷ in certain groups of postmenopausal women. NICE guidance on the menopause considers that current use of HRT treatment compared with non-use for women in menopause is associated with a significantly lower risk of fragility fracture⁸, and this could be considered for use in certain women. Many of the treatments that have been used in postmenopausal osteoporosis have also been investigated in men with osteoporosis.⁵ There is no NICE guidance on

treatment of men, but in addition to strontium, several bisphosphonates^{9,-11}, teriparatide¹² and denosumab¹³ are also licensed for use in this group.

A risk assessment should be conducted in all patients on strontium ranelate to determine continued need for treatment, and alternative therapeutic options considered if needed (including a drug holiday). Specialist advice may need to be sought in cases where the alternative treatment options are/were not suitable.

References

1. Servier Laboratories Limited. Protelos. SPC, date of revision of text 09/2016: <http://www.medicines.org.uk/emc/medicine/15410>
2. NICE. Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women. Technology appraisal guidance [TA160]: 27 October 2008, last updated: 01 January 2011: <https://www.nice.org.uk/guidance/ta160>
3. NICE. Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women. Technology appraisal guidance [TA161].: 27 October 2008, last updated: 01 January 2011: <https://www.nice.org.uk/guidance/ta161/chapter/1-guidance>
4. Medicines and Healthcare products Regulatory Agency. Strontium ranelate: cardiovascular risk: 12 March 2014: <https://www.gov.uk/drug-safety-update/strontium-ranelate-cardiovascular-risk>
5. Scottish Intercollegiate Guidelines Network. Management of osteoporosis and the prevention of fragility fracture. March 2015: <http://sign.ac.uk/pdf/SIGN142.pdf>
6. Servier Laboratories Ltd. Protelos (strontium ranelate): Cessation of supply. Communication 31 May 2017.
7. NICE. Denosumab for the prevention of osteoporotic fractures in postmenopausal women. Technology appraisal guidance [TA204]: 27 October 2010: <https://www.nice.org.uk/guidance/TA204/chapter/1-guidance>
8. Merck Sharp & Dohme Limited. Fosamax. SPC. date of revision, 8 June 2016: <http://www.medicines.org.uk/emc/medicine/1175>
9. Warner Chilcott UK Limited. Actonel Once a Week 35 mg film-coated tablets. SPC, date of revision, 14/01/2016: <http://www.medicines.org.uk/emc/medicine/11591>
10. Novartis Pharmaceuticals UK Ltd. Aclasta 5 mg solution for infusion. SPC, date of revision, 02 December 2015: <http://www.medicines.org.uk/emc/medicine/181714.1>
11. Eli Lilly and Company Limited. Forsteo 20 micrograms/80 microlitres solution for injection in pre-filled pen. SPC, date of revision, 01 January 2016: <http://www.medicines.org.uk/emc/medicine/12561>
12. NICE. Menopause- clinical guideline- methods, evidence and recommendations: 12 November 2015: <https://www.nice.org.uk/guidance/ng23/evidence/full-guideline-559549261>
13. Amgen Ltd. Prolia. SPC, date of revision, December 2016: <http://www.medicines.org.uk/emc/medicine/23127>

Acknowledgement

Scott Mercer, Principal Pharmacist, Immunotherapy (rheumatology, dermatology, allergy), Guy's and St Thomas' Hospital NHS Foundation Trust

Original document prepared by:

Yuet Wan, Medicines Information, Guy's and St Thomas' Hospital NHS Foundation Trust, 06 June 2017

Document modified by:

Name of individual at other centre using the product with modifications, centre, date

For all correspondence please contact:

Name of person at **base** hospital where memo is circulated (i.e. NOT the original author at Guy's and St Thomas' NHS Foundation Trust

Disclaimer: The content of some of this memo is based on **clinical opinion** from practitioners. Users should bear this in mind in deciding whether to base their policy on this document. Individual trusts should ensure that procedures for unlicensed medicines are followed where a foreign import drug is required in the interim.