

Discontinuation of strontium ranelate (Protelos®)

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.

Alendronic acid effervescent tablets are now included within the South Staffordshire formulary as an alternative option for patients with swallowing difficulties.

Within South Staffordshire the following bisphosphonates are included within the local formulary. For further information please visit <http://www.southstaffordshirejointformulary.nhs.uk/>.

Formulary Chapter 6: Endocrine system - Full Chapter		
06.06.02 Bisphosphonates and other drugs affecting bone metabolism		
NICE TA160 Osteoporosis - primary prevention		
NICE TA161: Osteoporosis - secondary prevention (including strontium ranelate)		
06.06.02 Bisphosphonates		
Alendronic Acid 	First Choice 	First Line Choice - Prescribe generically as 70mg once weekly. Combination products with Vitamin D are not on the formulary. People at risk of osteoporosis need to maintain an adequate intake of Calcium and Vitamin D; Vitamin D dosage should be 800iu per day.
Risedronate 	Formulary 	People at risk of osteoporosis need to maintain an adequate intake of Calcium and Vitamin D; Vitamin D dosage should be 800iu per day.
Alendronic Acid Effervescent tablets (Binosto) 	Formulary 	70mg effervescent Tablets Please note these are for patients with swallowing difficulties only. People at risk of osteoporosis need to maintain an adequate intake of Calcium and Vitamin D; Vitamin D dosage should be 800iu per day.
Ibandronic Acid (Bondronat) 	Formulary 	Bondronat Tablets 50mg Therapeutic indications Ibandronic acid is indicated in adults for prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases. People at risk of osteoporosis need to maintain an adequate intake of Calcium and Vitamin D; Vitamin D dosage should be 800iu per day .
Ibandronic Acid injection (Bonviva®) 	Formulary 	Bonviva Tablets 15mg Licensed for osteoporosis for Specialist Initiation
Sodium Clodronate 	Formulary 	
Disodium Pamidronate 	Restricted 	

References

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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>
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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

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