



Correspondence from Servier Laboratories on strontium ranelate

NPS received the following correspondence from the Therapeutics Committee of the Australian and New Zealand Bone & Mineral Society (ANZBMS) in response to the RADAR article *Strontium Ranelate for postmenopausal osteoporosis*, published 1 October 2007. NPS's reply is underneath.

“Strontium ranelate has been shown to reduce the risk of vertebral and non-vertebral fractures in two large trials, in patients with and without fractures at baseline, in postmenopausal women with osteoporosis or osteopenia and in women over 80 years of age. The ANZBMS notes that the effect size on non-vertebral fractures is comparable with the bisphosphonates. The drug reduces fractures within the first 12 months of the beginning of therapy and the benefits are sustained for 5 years. These features make it a first line option, not a second line agent to be used only after other therapy.”

This commentary was written in response to statements about strontium ranelate made by the NPS.

Servier agrees with the ANZBMS commentary and welcomes the decision of the PBS to allow usage of strontium ranelate (Protos) in postmenopausal women without a fracture (aged ≥ 70 years, BMD T-score ≤ -3.0) as well as in postmenopausal women who have already suffered a minimal trauma fracture.

Strontium ranelate (Protos) has marketing approval for treatment of postmenopausal osteoporosis to reduce the risk of fracture. Servier does not suggest use the product in any way incompatible with that described in the Approved Product Information.

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NPS reply

The NPS RADAR review of strontium ranelate states that it may be used as initial therapy for postmenopausal osteoporosis. However, strontium has limited data for an effect on hip fracture, there is less experience of its use and its long-term safety profile is yet to be established. For these reasons, NPS RADAR and other independent reviews¹⁻³ have recommended strontium as an alternative therapy when alendronate or risedronate are contraindicated or not tolerated.

Evidence that strontium reduces hip fracture risk is limited to a post-hoc analysis of a high-risk subgroup of women (who were ≥ 74 years and had a BMD T-score ≤ -3.0) from the TROPOS trial.⁴ Statistically significant differences found in post-hoc subgroup analyses need to be interpreted with caution as they could be due to chance. Therefore the evidence that strontium reduces hip fracture risk is limited and requires confirmation. There are more robust data to support an effect of alendronate and risedronate on hip fracture risk in postmenopausal women with or without a previous fracture.⁵⁻⁷ Refer to the [NPS RADAR review](#) for more information.

There are unpublished 5-year efficacy data for strontium.⁸ There are published data for up to 7 years with risedronate,⁹ and up to 10 years with alendronate.^{10,11} As with any new drug, the full toxicity profile of strontium is yet to be established.

References

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