# Protelos (strontium ranelate) will remain available but with further restrictions

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## Information on Protelos

Protelos (strontium ranelate) is authorised in the EU to treat severe osteoporosis (a disease that makes bones fragile) in women who have been through the menopause and who are at high risk of fracture (broken bones) especially to reduce the risk of fractures of the spine and the hip. It is also used to treat severe osteoporosis in men who are at high risk of fracture.

## Information from the European Medicines Agency about the safety concern

In April 2013 Medicines Authority safety circular P10/2013 (April 2013) advised on new recommendations to the use of Protelos in patients with known circulatory problems and on the start of a further in depth evaluation of the benefits and risks of Protelos by the European Medicines Agency (EMA). The European Medicines Agency has now concluded its in depth review of Protelos and has recommended further restricting the use of the medicine to patients who cannot be treated with other medicines approved for osteoporosis. In addition these patients should continue to be evaluated regularly by their doctor and treatment should be stopped if patients develop heart or circulatory problems, such as uncontrolled high blood pressure or angina. As recommended in a previous review, patients who have a history of certain heart or circulatory problems, such as stroke and heart attack, use of the medicine should be under prescribers guidance.

**The EMAs recommendation will now be sent to the European Commission, which will then issue a final decision.**

## In Malta

### For Healthcare Professionals

Healthcare professionals, specifically rheumatologists, endocrinologists, internal medicine specialists, general practitioners, gynaecologists, geriatricians and pharmacists will receive a letter from *Les Laboratoires Servier Malta* informing them of the updated recommendations on the use of Protelos. In brief, the letter will advise them of the following:



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- Protelos should only be used to treat severe osteoporosis in postmenopausal women and 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;
- Protelos must not be used in patients with established, current or past history of ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease, or those with uncontrolled hypertension;
- Doctors should continue to base their decision to prescribe Protelos on an assessment of the individual patient's risks. The patient's risk of developing cardiovascular disease should be evaluated before starting treatment and on a regular basis thereafter, generally every 6 to 12 months;
- Protelos should be stopped if the patient develops ischaemic heart disease, peripheral arterial disease or cerebrovascular disease, or if hypertension is uncontrolled;
- Doctors should review their patients currently on Protelos as necessary.

Furthermore additional risk minimisation measures which include providing educational material to prescribers to ensure that only the appropriate patients are treated with the medicine will be submitted by *Les Laboratoires Servier* Malta and following Medicines Authority approval will be circulated the previously mentioned healthcare professionals. Importantly, the company is required to conduct further research to demonstrate the effectiveness of the new measures. The Committee concluded that given the benefits seen in preventing fractures in patients at high risk, Protelos should remain an option for patients with no history of cardiovascular disease who cannot take other medicines.

This final EMA recommendation on the use of Protelos was based on an analysis of pooled data from randomised studies in around 7,500 post-menopausal women with osteoporosis. The results showed an increased risk of myocardial infarction with Protelos as compared with placebo (1.7% versus 1.1 %), with a relative risk of 1.6 (95% CI, 1.07 to 2.38), and an increased risk of venous thrombotic and embolic events — 1.9% versus 1.3 % with a relative risk of 1.5 (95% CI, 1.04 to 2.19).

Available data do not show evidence of an increased cardiovascular risk in patients without established, current or past history of ischaemic heart disease, peripheral arterial disease or cerebrovascular disease, or in those without uncontrolled hypertension.

Regarding the benefits, the efficacy data showed an effect in preventing fractures, including in patients at high risk of fracture.

**Information to patients**

- Protelos will only be prescribed for preventing fractures in post-menopausal women and men with severe osteoporosis who have a high risk of fracture and cannot be treated with other medicines approved for osteoporosis.



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- Before starting treatment, your doctor will assess your risk of heart disease and high blood pressure and continue to check your risk at regular intervals during treatment.
- You should not take Protelos if you have or have had heart or circulatory problems such as stroke, heart attack, or obstruction of the blood flow in the arteries, unless under the strict supervision of your prescriber.
- Your treatment with Protelos will be stopped if you develop heart or circulatory problems during treatment.
- If you have any questions, speak to your doctor or pharmacist.

For more information please visit **www.ema.europa.eu**

## Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on PROTELOS. Suspected Adverse Drug Reactions (side effects)or medication errors may be reported using the Medicines Authority ADR reporting form or online at **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

**Dr John J Borg PhD (Bristol)**
**Post-licensing Director**

***Healthcare professionals and patients are encouraged to regularly check the Medicine Authority website for product safety updates as these are issued on an ongoing basis.***



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