



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Recommendation to restrict the use of Protelos/Osseor (strontium ranelate)

CHMP confirms recommendation from the PRAC

The EMA's Committee for Medicinal Products for Human Use (CHMP) has recommended a restriction in the use of the osteoporosis medicine Protelos/Osseor, following an assessment of data showing an increased risk of serious heart problems. The CHMP recommended that Protelos/Osseor should only be used to treat severe osteoporosis in postmenopausal women at high risk of fracture and severe osteoporosis in men at increased risk of fracture. Additional measures, including restrictions in patients with heart or circulatory problems, were also recommended to minimise the heart risks of these medicines.

The CHMP recommendation is based on the advice of the Pharmacovigilance Risk Assessment Committee (PRAC), which evaluated Protelos/Osseor as part of a routine benefit-risk assessment. During the assessment, data from clinical studies in post-menopausal women were evaluated, showing a higher risk of heart attack with Protelos/Osseor than with placebo, with no observed increase in mortality risk. Given the other serious risks (blood clots and rare serious skin reactions) previously identified with the medicine, the PRAC concluded that certain restrictions in the use of the medicine should be in place for the benefit-risk balance to remain favourable and that a further in-depth evaluation of the benefits and risks of the medicine was needed.

The CHMP agreed with the PRAC's recommendations and this opinion will be sent to the European Commission for a legally binding decision. A further wide-ranging evaluation of the benefits and risks of Protelos/Osseor will now be conducted by PRAC and CHMP. In the meantime, the current recommendations are intended to minimise the risk of serious heart problems.

### Information to patients

Following an assessment of data showing an increased risk of heart problems with Protelos/Osseor, some changes in the way the medicine is used have been recommended:

- Protelos/Osseor should only be used to treat severe osteoporosis in postmenopausal women at high risk of fracture and severe osteoporosis in men at increased risk of fracture. If you are taking Protelos/Osseor, your doctor will assess whether you have severe osteoporosis or are at high risk of fracture, and consider whether to stop your treatment.



- Protelos/Osseor must not be used in patients with high blood pressure that is not properly controlled or in patients with a current or past history of any of the following:
  - ischaemic heart disease (such as angina or a heart attack);
  - peripheral arterial disease (obstruction of the blood flow in the arteries, usually in the legs);
  - cerebrovascular disease (diseases affecting the blood vessels in the brain, such as stroke).
- If you continue to be treated with Protelos/Osseor, your doctor will check your risk of heart disease and high blood pressure at regular intervals during treatment.
- If you have any questions, speak to your doctor or pharmacist.

### **Information to healthcare professionals**

Healthcare professionals in the EU Member States will receive a letter informing them of the updated recommendations on the use of Protelos/Osseor. The letter will advise them of the following:

- Protelos/Osseor should only be used for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture and severe osteoporosis in men at increased risk of fracture.
- Protelos/Osseor is contraindicated in patients with a current or past history of ischaemic heart disease, peripheral arterial disease, or cerebrovascular disease, or in patients with uncontrolled hypertension.
- Treatment with Protelos/Osseor should only be started by a physician experienced in the treatment of osteoporosis.
- The physician should base their decision to prescribe Protelos/Osseor on an assessment of the individual patient's risks. The patient's risk of developing cardiovascular disease should be evaluated before and at regular intervals during treatment
- Treatment should be stopped if the patient develops ischaemic heart disease, peripheral arterial disease or cerebrovascular disease or if hypertension becomes uncontrolled.

The EMA's recommendations are based on an analysis of pooled data from randomised studies in around 7,500 post-menopausal women with osteoporosis. The results showed an increase in the risk of heart attack with Protelos/Osseor as compared with placebo (1.7% versus 1.1 %), with a relative risk of 1.6 (95% confidence interval, 1.07 to 2.38). There was also an imbalance in the number of serious heart events seen with the medicine in two other studies, one in men with osteoporosis and another in patients with osteoarthritis. No increased risk in mortality was observed.

The EMA will keep healthcare professionals informed of the outcome of the further evaluation of the benefits and risks of Protelos/Osseor.

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### **More about the medicine**

Protelos/Osseor was authorised in the EU in 2004 for the treatment of osteoporosis (a disease that makes bones fragile) in women who have been through the menopause, to reduce the risk of fractures in the spine and the hip. In 2012, its authorisation was extended to include the treatment of osteoporosis in men at increased risk of fractures.

In March 2012, following concerns over the risks of blood clots in the veins (VTE, venous thromboembolism) and severe allergic skin reactions, the EMA completed a review of benefits and risks

of Protelos/Osseor and recommended that the medicine must not be used in patients with blood clots or a history of blood clots, as well as in patients who were temporarily or permanently immobilised. In addition, warnings on the serious skin reactions were included in the product information. More information on the previous EMA review can be found [here](#).

#### **More about this assessment**

The assessment by the PRAC was a routine benefit-risk assessment, known as a Periodic Safety Update Report (PSUR) assessment. PSURs are periodic reports on the benefit-risk balance of a medicine submitted by companies at defined time points after a medicine's authorisation. During the assessment of PSURs, the Agency evaluates any new risks identified in order to determine whether the balance of benefits and risks of a medicine has changed and makes immediate proposals in relation to such risks.

Following the assessment by the PRAC, now endorsed by the CHMP, the CHMP opinion will be sent to the European Commission, which will issue a legally binding decision.

A further in-depth evaluation of all the benefits and risks of Protelos/Osseor will now be started.

#### **Contact our press officers**

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Monika Benstetter or Martin Harvey Allchurch

Tel. +44 (0)20 7418 8427

E-mail: [press@ema.europa.eu](mailto:press@ema.europa.eu)