



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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PRAC recommends restriction in the use of Protelos/Osseor

PRAC recommendation to be considered by CHMP for final opinion

During its meeting of 8 to 11 April 2013, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommended restrictions in the use of Protelos/Osseor (strontium ranelate), following the evaluation of data showing an increased risk of heart problems, including heart attacks.

Protelos and Osseor are identical medicines used in the treatment of osteoporosis.

The outcome of the PRAC assessment will be sent to the Agency's Committee for Medicinal Products for Human Use (CHMP), which will adopt a final opinion at the next CHMP meeting of 22 to 25 April 2013.

Why was Protelos/Osseor reviewed by the PRAC?

The PRAC review of Protelos/Osseor was carried out as part of a routine benefit-risk assessment of the medicine (known as a Periodic Safety Update Report or PSUR assessment), which included data showing an increased risk of heart problems, including heart attacks. The key data were obtained from clinical studies in about 7,500 patients.

What are the PRAC conclusions?

The data from clinical studies showed that there was an increased risk of a heart attack in postmenopausal women taking Protelos/Osseor compared with those taking placebo (a dummy treatment), although there was no increase in deaths. On the whole, the data were of concern given other serious risks (blood clots and rare serious skin reactions) that were identified in a previous EMA review in 2012. The PRAC therefore concluded that a further expedited in-depth evaluation of the benefits and risks of the medicine is needed. While this evaluation is carried out, the PRAC recommends that changes should be implemented to the prescribing information for Protelos/Osseor. The need for a further evaluation and the following changes to the product information will be considered by the CHMP:

- Protelos/Osseor should only be used for the treatment of severe osteoporosis in postmenopausal women at high risk for fracture and severe osteoporosis in men at increased risk of fracture.



- Protelos/Osseor should not be used in patients with current or past history of ischaemic heart disease (such as angina or a heart attack), peripheral arterial disease (obstruction of large blood vessels, often in the legs) or cerebrovascular disease (diseases affecting the blood vessels supplying the brain, such as stroke).
- Protelos/Osseor should not be used in patients with hypertension (high blood pressure) that is not adequately controlled by treatment.

What will happen next?

The PRAC recommendations will now be sent to the CHMP for consideration at the next CHMP meeting of 22 to 25 April 2013. The Agency will make public information on any further in-depth benefit-risk evaluation of Protelos/Osseor.

The final CHMP opinion, together with full advice for patients and healthcare professionals, will be made public. When the final opinion is taken, healthcare professionals in the EU will receive a letter with detailed information on the appropriate actions to be taken. Patients who have any questions should speak to their doctor or pharmacist.

The final CHMP opinion will be forwarded to the European Commission, which will issue a final decision.

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 updated in the product information. More information on the previous EMA review can be found [here](#).

More about PSUR assessments

The review carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the committee responsible for the evaluation of the safety of human medicines, is part of a routine benefit-risk assessment, known as Periodic Safety Update Report (PSUR) assessment.

PSURs are periodic reports on the benefit-risk balance of a medicine. They are submitted by companies at defined time points after a medicine's authorisation. During its assessment of PSURs, the Agency evaluates any risks identified for a medicine to assess whether the balance of benefits and risks of a medicine has changed.

The PRAC recommendation will now be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for all questions concerning medicines for human use, which will adopt an opinion.