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Review of Protelos/Osseor (strontium ranelate) started

The European Medicines Agency has started a review of Protelos/Osseor, a medicine containing strontium ranelate used for treating osteoporosis.

The review has been started following a recent routine evaluation of safety data showing an increased risk of serious heart problems, including heart attack, with the medicine. In order to minimise the serious heart problems identified, the EMA recommended that the medicine's use should be restricted to treating only severe osteoporosis in postmenopausal women at high risk of fractures and men at increased risk of fracture. Additional measures were also recommended to minimise the medicine's heart risks, including restrictions in patients with existing heart or circulatory problems. However, given the other serious risks previously identified with the medicine, including blood clots and rare serious skin reactions, the Agency's scientific committees also concluded that there was a need to review all the available data on the benefits and risks of the medicine in further depth.

The Agency will now carry out this in-depth review, including a detailed analysis of the latest available data on the risk of heart problems.

More about the medicine

Protelos and Osseor are identical medicines containing the active substance strontium ranelate. They were 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, this authorisation was extended to include the treatment of osteoporosis in men at increased risk of fractures.

Exactly how strontium works in osteoporosis is not fully understood, but it is known to stimulate bone formation and reduce bone breakdown.

More information about the previous EMA recommendations on Protelos/Osseor can be found here.

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More about the procedure

The review of Protelos/Osseor has been started at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004. It will follow the procedural steps laid out in Article 31 of Directive 2001/83.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendation will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for all questions concerning medicines for human use, which will adopt a final opinion.

The CHMP opinion will be sent to the European Commission for a legally binding decision.