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PRAC recommends suspending use of Protelos/Osseor (strontium ranelate)

Recommendation by PRAC to be considered by CHMP for final opinion

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended that Protelos/Osseor should no longer be used to treat osteoporosis.

In April 2013 the Agency had recommended restricting the use of Protelos/Osseor to reduce the risk of heart problems. These recommendations were the result of a routine benefit-risk assessment and it was also decided at the time that there was a need for a further in-depth review.

The PRAC has now conducted an in-depth review taking into account available data on the benefits and risks of the medicine. The Committee noted that for every 1,000 patient-years[1] there were 4 more cases of serious heart problems (including heart attacks) and 4 more cases of blood clots or blockages of blood vessels with Protelos/Osseor than with placebo (a dummy treatment). In addition, Protelos/Osseor is associated with a number of other risks, such as serious skin reactions, disturbances in consciousness, seizures (fits), liver inflammation and reduced number of blood cells.

The Committee also questioned the evidence on the extent to which the restrictions recommended in April 2013 reduced the cardiovascular risk and how well the restrictions work in clinical practice, particularly as the medicine is used for long-term treatment in elderly patients.

With regard to its benefits, Protelos/Osseor has been shown to have a modest effect in osteoporosis, preventing about 5 non-spinal fractures, 15 new spinal fractures and 0.4 hip fractures for every 1,000 patient-years.

The PRAC weighed the benefits of the medicine against the known risks and concluded that the balance was no longer favourable and recommended Protelos/Osseor be suspended until there are new data showing a favourable balance in a defined patient group.

The PRAC recommendation will now be sent to the Agency's Committee for Medicinal Products for Human Use (CHMP), which is expected to issue the Agency's final opinion at its meeting of 20 to 23 January 2014.

[1] Equivalent to 1,000 patients being treated for 1 year.

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More about the medicine

Protelos/Osseor (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) in the spine and the hip. It is also used to treat severe osteoporosis in men who are at increased risk of fracture.

More about the procedure

This in-depth review of the benefits and risks of Protelos/Osseor was initiated in May 2013 at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

The first stage of this review has now been conducted by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which has made a set of recommendations.

The PRAC recommendations will now be sent to the Agency's Committee for Medicinal Products for Human Use (CHMP), which will adopt the Agency's final opinion. The CHMP opinion will be forwarded to the European Commission, which will then issue a final decision.

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