24 May 2012
EMA/311245/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Osseor

strontium ranelate

On 24 May 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Osseor. The marketing authorisation holder for this medicinal product is Les Laboratoires Servier. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:
"Treatment of osteoporosis in men at increased risk of fracture"

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Osseor will be as follows[2]:

"OSSEOR is indicated in adults for:

- Treatment of osteoporosis in postmenopausal women to reduce the risk of vertebral and hip fractures (see section 5.1).

- Treatment of osteoporosis in men at increased risk of fracture (see section 5.1)."

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended indication.

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