25 April 2014
Committee for Medicinal Products for Human Use (CHMP)
EMA/CHMP/222395/2014
EMEA/H/C/000561/PSUV/0037

Osseor

International non-proprietary name: strontium ranelate

Procedure No. EMEA/H/C/000561/PSUV/0037

Period covered by the PSUR: 22 September 2012 - 21 September 2013

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Protelos and Osseor, the scientific conclusions of PRAC are as follows:

A significant increased reporting rate of dyslipidaemia was seen in the group treated with strontium ranelate *versus* placebo following the review of the study report of the study CL3-12911-018; 8.7% *vs.* 4.9% (OR=1.86 [1.15; 3.03]) in the treatment of osteoarthritis. The analysis carried out for dyslipidaemia in the authorised indication showed similar results; 8.2% in the strontium ranelate group *vs.* 6.3% in placebo group OR=1.33 [1.11; 1.58].

No confirmation of increase in lipid values could be seen in available biological results in the PMO sub-population and no support in the literature for a mechanistic rational has been found by the MAH. Data from patients with a reported adverse event of dyslipidaemia is too scarce to draw any firm conclusions and data sufficient to fully refute the signal hyperlipidaemia is missing. Based on the adverse event reporting in clinical studies, hyperlipidaemia is considered a new identified risk for strontium ranelate. The PRAC therefore recommends that the adverse reaction hypercholesterolaemia should be added to section 4.8 in the SmPC. The Package Leaflet should be updated accordingly. The PRAC does not consider that hyperlipidaemia needs to be added to the list of safety concerns in the RMP, since more serious cardiovascular risks are already handled in the RMP.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Protelos and Osseor, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance strontium ranelate is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisations should be varied.