22 May 2025
EMA/305951/2025
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): denosumab (indicated for osteoporosis and for bone loss associated with hormone ablation in prostate cancer)

Procedure No. EMEA/H/C/PSUSA/00000954/202409

Period covered by the PSUR:
25/09/2021 To: 25/09/2024

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for denosumab (indicated for osteoporosis and for bone loss associated with hormone ablation in prostate cancer), the scientific conclusions of PRAC are as follows:

In view of available data on a reduction in bone mineral density following denosumab discontinuation from clinical trial(s) and also described in recent published literature, the PRAC Rapporteur concluded that the product information of products containing denosumab (indicated for osteoporosis and for bone loss associated with hormone ablation in prostate cancer) should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for denosumab (indicated for osteoporosis and for bone loss associated with hormone ablation in prostate cancer) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing denosumab (indicated for osteoporosis and for bone loss associated with hormone ablation in prostate cancer) is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.