22 May 2025
EMA/CHMP/161299/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Conexxence

denosumab

On 22 May 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Conexxence, intended for the treatment of osteoporosis in women who have been through menopause, bone loss linked to hormone ablation in men with prostate cancer who are at increased risk of fractures, and bone loss in adults linked to long-term treatment with systemic glucocorticoid. The applicant for this medicinal product is Fresenius Kabi Deutschland GmbH.

Conexxence will be available as a 60 mg solution for injection. The active substance of Conexxence is denosumab, a drug for the treatment of bone diseases (ATC code: M05BX04). Denosumab is a human monoclonal IgG2 antibody that targets the protein RANKL, which is essential for the formation, function and survival of osteoclasts, the cell type responsible for bone resorption. Denosumab binds to RANKL with high affinity and specificity, preventing the interaction between RANKL and RANK. This leads to a reduction in osteoclast numbers and function and a decrease in bone resorption in cortical and trabecular bones.

Conexxence is a biosimilar medicinal product. It is highly similar to the reference product Prolia (denosumab), which was authorised in the EU on 26 May 2010. Data show that Conexxence has comparable quality, safety and efficacy to Prolia (denosumab). More information on biosimilar medicines can be found here.

The full indication is:

> Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures. In postmenopausal women denosumab significantly reduces the risk of vertebral, non-vertebral and hip fractures.
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> Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures (see section 5.1). In men with prostate cancer receiving hormone ablation, denosumab significantly reduces the risk of vertebral fractures.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture (see section 5.1).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.