25 April 2025
EMA/CHMP/132987/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Enwylma

denosumab

On 25 April 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 Enwylma, intended for the prevention of bone complications in adults with advanced cancer involving bone and the treatment of adults and skeletally mature adolescents with giant cell tumour of bone.

The applicant for this medicinal product is Zentiva k.s.

Enwylma will be available as a 120 mg solution for injection. The active substance of Enwylma 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. Increased osteoclast activity stimulated by RANKL plays a key role in bone destruction in patients with advanced cancer of bones. 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.

Enwylma is a biosimilar medicinal product. It is highly similar to the reference product Xgeva (denosumab), which was authorised in the EU on 13 July 2011. Data show that Enwylma has comparable quality, safety and efficacy to Xgeva. More information on biosimilar medicines can be found here.

The full indication is:

> Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone (see section 5.1).
>
> Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

[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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Enwylma should be administered under the responsibility of a healthcare professional.

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.