26 February 2026
EMA/CHMP/48966/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zandoriah

teriparatide

On 26 February 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zandoriah, intended for the treatment of osteoporosis in adults.

The applicant for this medicinal product is Cinnagen Co. Unipessoal Lda.

Zandoriah will be available as a 20 µg/80 µl solution for injection in pre-filled pens. The active substance of Zandoriah is teriparatide, a parathyroid hormone analogue (ATC code: H05AA02). It acts on the parathyroid hormone receptor with the same affinity as human parathyroid hormone and, by binding to this receptor, exerts the same effects on bone metabolism.

Zandoriah is a biosimilar medicinal product. It is highly similar to the reference product Forsteo, which was authorised in the EU on 10 June 2003. Data show that Zandoriah has comparable quality, safety and efficacy to Forsteo. More information on biosimilar medicines can be found here.

The full indication is:

> Teriparatide is indicated in adults.
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> Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture (see section 5.1). In postmenopausal women, a significant reduction in the incidence of vertebral and non-vertebral fractures but not hip fractures has been demonstrated.
>
> Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for 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.

[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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