



27 January 2022
EMA/CHMP/40683/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Sondelbay

teriparatide

On 27 January 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sondelbay, intended for the treatment of osteoporosis.

The applicant for this medicinal product is Accord Healthcare S.L.U.

Sondelbay will be available as a 20 µg/80 µl solution for injection. The active substance of Sondelbay is teriparatide, the active aminoterminal fragment of human parathyroid hormone (ATC code: H05AA02). It acts via the receptor for parathyroid hormone and has an anabolic effect on bone.

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

The full indication is:

Sondelbay is indicated in adults.

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 have 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 in the European public assessment report (EPAR) and made available 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

