



10 November 2022
EMA/CHMP/863898/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Kauliv teriparatide

On 10 November 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 Kauliv, intended for the treatment of osteoporosis. The applicant for this medicinal product is Strides Pharma Cyprus.

Kauliv will be available as a 20 µg/80 µl solution for injection. The active substance of Kauliv is teriparatide, the active aminoterminal fragment of human parathyroid hormone (ATC code: H05AA02). Teriparatide 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.

Kauliv is a biosimilar medicinal product. It is highly similar to the reference product Forsteo. Data show that Kauliv has comparable quality, safety and efficacy to Forsteo. More information on biosimilar medicines can be found [here](#).

The full indication is:

Kauliv 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 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 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

