10 November 2016
EMA/CHMP/714649/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Terrosa

teriparatide

On 10 November 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Terrosa, intended for the treatment of osteoporosis. The applicant for this medicinal product is Gedeon Richter plc.

Terrosa will be available as solution for injection (20 micrograms/80 microliters). The active substance of Terrosa 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.

The expected benefits with Terrosa are its ability to increase bone mineral density in the lumbar spine and hip and to reduce the risk of vertebral and non-vertebral fractures (other than the hip) in postmenopausal women with osteoporosis. The most common side effect is pain in the arm or leg.

Terrosa is a biosimilar medicinal product highly similar to the reference product Forsteo. Studies have shown Terrosa to have comparable quality, safety and efficacy to Forsteo.

The full indication is:

"Terrosa 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

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