EMA/CHMP/341130/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Qutavina

teriparatide

On 25 June 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Qutavina, intended for the treatment of osteoporosis. The applicant for this medicinal product is EuroGenerics Holdings B.V.

Qutavina will be available as a solution for injection (20 micrograms/80 microlitres). The active substance of Qutavina 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.

Qutavina 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 Qutavina has comparable quality, safety and efficacy to Forsteo. More information on biosimilar medicines can be found here.

The full indication is:

Qutavina 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union