15 September 2022
EMA/CHMP/734147/2022
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Teriparatide SUN

teriparatide

On 15 September 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 Teriparatide SUN, intended for the treatment of osteoporosis in adults. The applicant for this medicinal product is Sun Pharmaceutical Industries Europe B.V.

Teriparatide SUN will be available as a 20 µg/80 µl solution for injection. The active substance of Teriparatide SUN is teriparatide, which belongs to the parathyroid hormones and analogues involved in the calcium homeostasis (ATC code: H05AA02) and stimulates bone formation by direct effects on osteoblasts and indirectly increasing the absorption of calcium in the intestines and tubular re-absorption of calcium and excretion of phosphate by the kidney.

The expected benefits with Teriparatide SUN 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 in patients taking teriparatide is pain in the arms or legs.

Teriparatide SUN is a hybrid medicine[2] of Forsteo which has been authorised in the EU since 10 June 2003. Teriparatide SUN contains the same active substance as Forsteo, although for Teriparatide SUN the substance is chemically synthesised and for Forsteo it is of biological origin.

Studies have demonstrated the satisfactory quality of Teriparatide SUN, and its bioequivalence to the reference product Forsteo.

The full indication is:

> Teriparatide SUN 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

[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
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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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.