



FORTEO® BIOSIMILAR CANDIDATE (RECOMBINANT TERIPARATIDE)

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Osteoporosis: the silent disease

Often going undiagnosed, osteoporosis accounts for more than 8.9 million fractures worldwide equating to an osteoporotic fracture every 3 seconds. 1 in 3 women and 1 in 5 men over 50 experience an osteoporotic fracture during their lifetime (IOF).

200 million women worldwide are affected by osteoporosis accounting for 61% of total osteoporotic fractures.

What is osteoporosis?

Osteoporosis (meaning porous bone) is a progressive bone disease that is characterised by a decrease in bone mass and density which leads to an increased risk of fracture. Loss of bone occurs silently and progressively, often with no symptoms until the first fracture.

For people with osteoporosis, bone loss outpaces the growth of new bone. The disease can be classified as primary type 1, primary type 2 or secondary. Osteoporosis most common in women after the menopause is referred as primary type 1 whilst primary type 2 is seen in both women and men over the age of 75.

NORMAL BONE



OSTEOPOROSIS



SEVERE OSTEOPOROSIS



Deterioration of bone structure at the various stages of osteoporosis

Recombinant Teriparatide

Teriparatide is the only known therapy for new bone formation and stimulation of bone tissue in severe osteoporosis patients with no known side effects. It has been approved by the FDA (Nov 2002) for treatment of osteoporosis in men and postmenopausal women with increased risk of fracture.

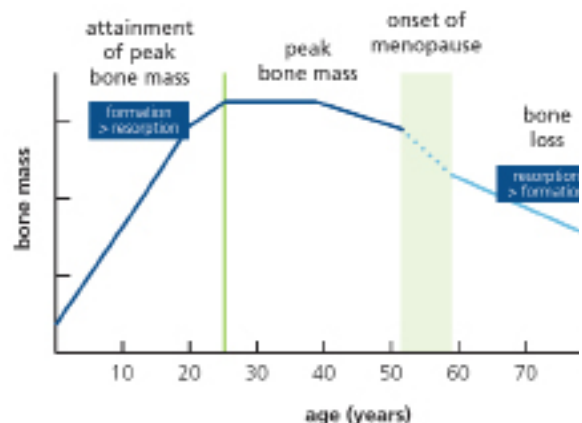
- A polypeptide that consists of the 1-34 amino acid fragment of human parathyroid hormone, the biologically active N-terminal region.
- A single daily subcutaneous injection for up to 24 months. Treatment results in new bone formation and increased bone mineral density.
- Several patents exist in the United States, Europe, Canada and Japan protecting the teriparatide's originator until 2018 / 2019.
- Injection administered into the thigh or abdominal wall via an injection pen prefilled with 28 days dose (20µg / day).

Teriparatide has a molecular weight of 4117.8 D.

Paras Biopharmaceuticals' recombinant teriparatide will be licensed under the brand name: **TeriShield™**.

KNOWN AS THE **SILENT EPIDEMIC**, ONCE THOUGH TO BE A NATURAL PART OF AGING AMONGST WOMEN, **OSTEOPOROSIS** IS NO LONGER CONSIDERED AGE- OR GENDER-RELATED.

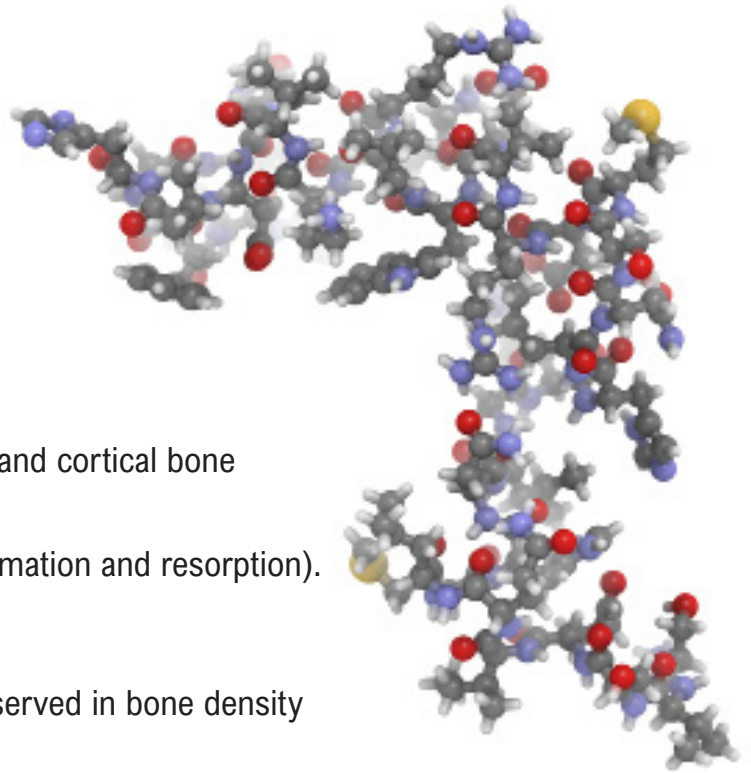
Bone mass rapidly decreases with the onset of the menopause



Action

Teriparatide has the following actions:

- Increases serum calcium and decreases serum phosphorus.
- Increases urinary calcium excretion.
- Increases the median serum concentration of 1,25-dihydroxyvitamin D.
- Increases serum acid concentrations.
- Stimulates new bone formation on trabecular and cortical bone surfaces.
- Increases bone turnover (markers of bone formation and resorption).
- Increases bone mass density.
- Improvements as great as 15% have been observed in bone density within 6 months of treatment.



RECOMBINANT TERIPARATIDE

PRODUCT SUMMARY

Teriparatide is the only known therapy for new bone formation and simulation of bone tissues in severe osteoporosis patients with no known side effects. A single daily subcutaneous injection for up to 24 months results in new bone formation and increases bone mineral density.

- BRAND NAME: Forteo® by Eli Lilly, USA
- ACTIVE INGREDIENT: Teriparatide Acetate [rDNA origin]
- DESCRIPTION: Recombinant form of Parathyroid hormone
- TARGET GROUP: Treatment of osteoporosis in men and postmenopausal women
- PRODUCT PATENT EXPIRY: expired





Paras Biopharmaceuticals' biologics candidates / technologies under development

- Biosimilar candidate to Forteo® (Teriparatide)
- Biosimilar candidate to Kineret® (Anakinra)
- Biosimilar candidate to Novolog® (Insulin Aspart)
- Biosimilar candidate to Nplate® (Romiplostim)
- Biosimilar candidate to Elitek® (Rasburicase)

Disclaimer:

Products under patents are part of our research projects. These products may be offered for further development only in those countries where patents have expired. For the latest status, please contact Paras Biopharmaceuticals Finland Oy.

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