

SUMMARY OF PRODUCT

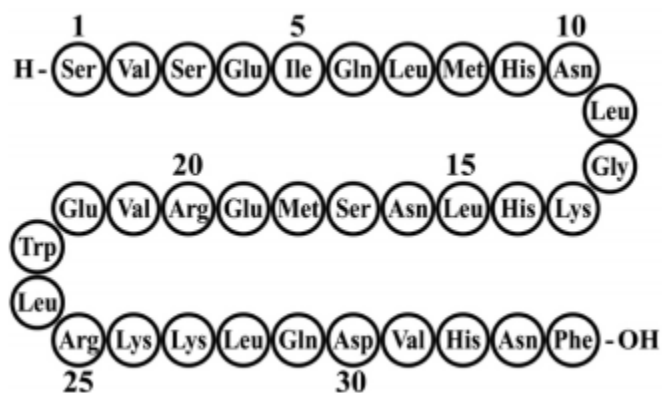
STRUCTURE

Teriparatide (rDNA origin) is a single chain peptide and contains recombinant human parathyroid hormone (1-34), [rhPTH(1-34)], which has an identical sequence to the 34 N-terminal amino acids (the biologically active region) of the 84-amino acid human parathyroid hormone(PTH) which is a single-chain polypeptide composed. It has no disulfide bonds and no glycosylation sites. Teriparatide (rDNA origin) is manufactured using a strain of Escherichia coli modified by recombinant DNA technology. Parathyroid hormone (PTH) is a single-chain polypeptide composed of 84 amino acids.

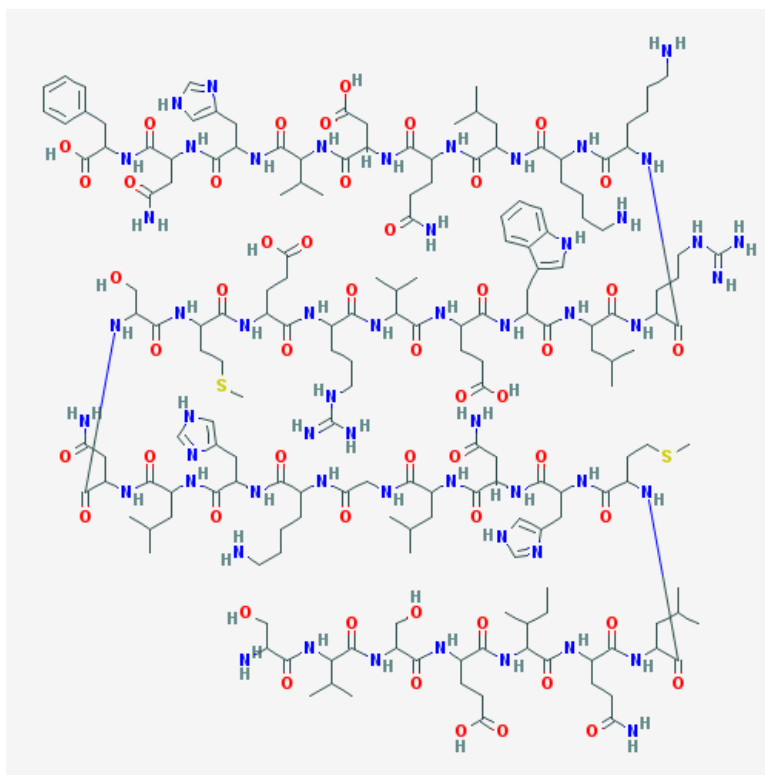
Teriparatide has a molecular weight of 4117.8 Daltons. The peptide is highly flexible, with transient helical regions. Parathyroid hormone (PTH) is the primary regulator of calcium and phosphate metabolism in bone and kidney and once-daily administration of PTH is known to stimulate bone formation.

Amino Acid Sequence of Teriparatide

Amino Acid Sequence of Teriparatide is shown below:



Structural Formula:



Nomenclature information of Teriparatide.

Recommended International Nonproprietary Name (INN)	Teriparatide
Anatomical Therapeutic Chemical (ATC) code	H05AA02
Chemical Name	Parathyroid hormone (1-34) (human)
Chemical Abstracts Service (CAS) registry number	52232-67-4
Molecular Formula	C ₁₈₁ H ₂₉₁ N ₅₅ O ₅₁ S ₂
Molecular weight	~ 4 KDa

Name of the medicinal product

CinnoPar® 600 mcg/2.4 ml solution for injection in pre-filled pen.

Reference Product

Forsteo from Eli Lilly

Quantitative and Qualitative composition

Each 2.4 mL multiple dose syringe contains 600 mcg of Teriparatide. (Corresponding to 250 micrograms per mL).

Teriparatide is a recombinant human parathyroid hormone analogue, which is produced by recombinant DNA technology in an Ecoli cell expression system.

Each syringe of CinnoPar® consists of Mannitol, m-Cresol, Glacial acetic acid, Anhydrous Sodium Acetate, Hydrochloric acid (for pH adjustment), Sodium hydroxide (for pH adjustment) and Water for injection.

Therapeutic indications

Osteoporosis in postmenopausal women

Osteoporosis in men

Glucocorticoid-induced osteoporosis

Pharmacological properties

Pharmaco-therapeutic group: Calcium homeostasis, parathyroid hormones and analogues, ATC code: H05 AA02.

Route of Administration

SC