PA011FSRI04

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Teriparatide Injection I.P. (r-DNA origin)
Forteo®

(600mcg/2.4mL, Solution for injection in a pre-filled pen)

NAME OF THE MEDICINAL PRODUCT

Forteo® 600mcg/2.4mL, solution for injection, in pre-filled pen.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of Teriparatide Injection I.P. contains: 250 mcg Teriparatide I.P. (r-DNA origin) as active ingredient, 0.41 mg Glacial Acetic Acid I.P. as buffering agent, 0.10 mg Sodium Acetate (Anhydrous) I.P. as buffering agent, 45.4 mg Mannitol I.P. as tonicity modifier, 3.0 mg Metacresol Ph. Eur. as preservative, Hydrochloric Acid Solution I.P. 10% q.s. and Sodium Hydroxide Solution I.P. 10% q.s. for pH adjustment, Water for Injection I.P. q.s. 1 mL.

Teriparatide, rhPTH (1-34), produced in E. coli, using recombinant DNA technology, is identical to the 34 N-terminal amino acid sequence of endogenous human parathyroid hormone.
For a full list of excipients, (see section *List of excipients*)

PHARMACEUTICAL FORM

Solution for injection in a pre-filled pen.

Colourless, clear solution

CLINICAL PARTICULARS

Therapeutic indications

Forteo® is indicated for the treatment of men and postmenopausal women with osteoporosis who are at a high risk of fracture. Forteo® increases BMD and reduces the risk of vertebral and non-vertebral fractures.

Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture (see section *Pharmacodynamic properties*).

Posology and method of administration

The recommended dose of Forteo® is 20 micrograms administered once daily by subcutaneous injection in the thigh or abdomen.

Patients must be trained to use the proper injection techniques (see section *Special precautions for disposal*). A User Manual is also available to instruct patients on the correct use of the pen.

The maximum total duration of treatment with Forteo® should be 24 months (see section *Special warnings and precautions for use*). The 24 month course of Forteo® should not be repeated over a patient's lifetime.
Patients should receive supplemental Calcium and vitamin D supplements if dietary intake is inadequate.
Following cessation of Forteo® therapy, patients may be continued on other osteoporosis therapies.

Use in renal impairment: Forteo® should not be used in patients with severe renal impairment (see section *Contraindications*). In patients with moderate renal impairment, Forteo® should be used with caution. No special caution is required for patients with mild renal impairement.

Use in hepatic impairment: no data are available in patients with impaired hepatic function (see section *Preclinical safety data*). Therefore Forteo® should be used with caution.

Paediatric population and young adults with open epiphyses: There is no experience in paediatric patients (less than 18 years). Forteo® should not be used in paediatric patients (less than 18 years), or young adults with open epiphyses.

Elderly patients: Dosage adjustment based on age is not required (see section *Pharmacokinetic properties*).

Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Pregnancy and lactation (see section Special warnings and precautions for use and Pregnancy and lactation)
- Pre-existing hypercalcaemia
- Severe renal impairment
- Metabolic bone diseases (including hyperparathyroidism and Paget's disease of the bone) other than primary osteoporosis or glucocorticoid-induced osteoporosis.
- Unexplained elevations of alkaline phosphatase
- Prior external beam or implant radiation therapy to the skeleton
- Patients with skeletal malignancies or bone metastases should be excluded from treatment with teriparatide.

Special warnings and precautions for use

Serum and Urine Calcium:

In normocalcemic patients, slight and transient elevations of serum calcium concentrations have been observed following teriparatide injection. Serum calcium concentrations reach a maximum between 4 and 6 hours and return to baseline by 16 to 24 hours after each dose of teriparatide. Routine calcium monitoring during therapy is not required. Therefore if any blood samples are taken from a patient, this should be done at least 16 hours after the most recent Forteo® injection.

Forteo® may cause small increases in urinary calcium excretion, but the incidence of hypercalciuria did not differ from that in the placebo-treated patients in clinical trials.

Urolithiasis:

Forteo® has not been studied in patients with active urolithiasis. Forteo® should be used with caution in patients with active or recent urolithiasis because of the potential to exacerbate this condition.

Orthostatic Hypotension:

In short-term clinical studies with Forteo®, isolated episodes of transient orthostatic hypotension were observed. Typically, an event began within 4 hours of dosing and spontaneously resolved within a few minutes to a few hours. When transient orthostatic hypotension occurred, it happened within the first several doses, was relieved by placing subjects in a reclining position, and did not preclude continued treatment.

Renal Impairment:

Caution should be exercised in patients with moderate renal impairment.

Younger Adult Population:

Experience in the younger adult population, including premenopausal women, is limited (see section *Pharmacodynamic properties*). Treatment should only be initiated if the benefit clearly outweighs risks in this population.

Women of childbearing potential should use effective methods of contraception during use of Forteo® . If pregnancy occurs, Forteo® should be discontinued.

Duration of Treatment:

Studies in rats indicate an increased incidence of osteosarcoma with long-term administration of teriparatide (see section Preclinical safety data). Until further clinical data become available, the recommended treatment time of 24 months should not be exceeded.

Interactions with other medicinal products and other forms of interaction

Forteo® has been evaluated in pharmacodynamic interaction studies with hydrochlorothiazide. No clinically significant interactions were noted.

Co-administration of raloxifene or hormone replacement therapy with Forteo® did not alter the effects of Forteo® on serum or urine calcium or on clinical adverse events.

In a study of 15 healthy subjects administered digoxin daily to steady state, a single Forteo® dose did not alter the cardiac effect of digoxin. However, sporadic case reports have suggested that hypercalcaemia may predispose patients to digitalis toxicity. Because Forteo® transiently increases serum calcium, Forteo® should be used with caution in patients taking digitalis

Fertility, pregnancy and lactation

Fertility
Studies in rabbits have shown reproductive toxicity (see section Preclinical safety data). The effect of teriparatide on human foetal development has not been studied. The potential risk for humans is unknown.
Pregnancy
Forteo® is contraindicated for use during pregnancy (see section *Contraindications*)

Breast –Feeding
Forteo® is contraindicated for use during breast-feeding. It is not known whether teripartide is excreted in human milk.

Women of childbearing potential / Contraception in females

Women of childbearing potential should use effective methods of contraception during use of Forteo®. If pregnancy occurs, Forteo® should be discontinued.

Effects on ability to drive and use machines

Forteo® has no or negligible influence on the ability to drive and use machines. Transient, orthostatic hypotension or dizziness was observed in some patients. These patients should refrain from driving or the use of machines until symptoms have subsided.

Undesirable effects

Of patients in the teriparatide trials, 82.8% of the Forteo® patients and 84.5% of the placebo patients reported at least 1 adverse event.

The most commonly reported adverse reactions in patients treated with Forteo® are nausea, pain in limb, headache and dizziness.

The undesirable reactions associated with the use of teriparatide in osteoporosis clinical trials and post-marketing exposure are summarized in the table below. The following convention has been used for the classification of the adverse reactions: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥ 1/1,000 to <1/100), rare (≥ 1/10,000 to <1/1,000) very rare (<1/10,000)

Table 1

Investigations *Uncommon:* Weight increased, Cardiac murmur, alkaline phosphatase increase
Cardiac disorders *Common:* Palpitations *Uncommon:* Tachycardia
Blood and lymphatic system disorders *Common:* Anaemia
Immune system disorder *Rare:* Anaphyliaxis
Nervous system disorders *Common:* Dizziness, Headache, Sciatica, Syncope
Ear and labyrinth disorders *Common:* Vertigo
Respiratory, thoracic and mediastinal disorders *Common:* Dyspnoea *Uncommon:* Emphysema
Gastrointestinal disorders *Common:* Nausea, Vomiting, Hiatus hernia, Gastroesophageal reflux disease *Uncommon:* Haemorrhoids
Renal and urinary disorders *Uncommon:* Urinary incontinence, Polyuria, Micturition urgency, nephrolithiasis *Rare:* Renal Failure/impairment
Skin and subcutaneous tissue disorders *Common:* Sweating increased
Musculoskeletal and connective tissue disorders *Very common*: Pain in limb *Common:* Muscle cramps *Uncommon:* Myalgia, Arthralgia, Back cramp/pain*
Metabolism and nutrition disorders *Common:* Hypercholesterolaemia *Uncommon:* Hypercalcemia greater than 2.76 mmol/L, Hyperuricemia *Rare:* Hypercalcemia greater than 3.25 mmol/L
Vascular disorders *Common:* Hypotension
General disorders and administration site conditions *Common:* Fatigue, Chest pain, Asthenia, Mild and transient injection site events, including pain, swelling, erythema, localised bruising, pruritis and minor bleeding at injection site. *Uncommon:* Injection site erythema, Injection site reaction *Rare:* Possible allergic events soon after injection: acute dyspnoea, oro/facial oedema, generalised urticaria, chest pain, oedema (mainly peripheral).
Psychiatric disorders *Common:* Depression

* Serious cases of back cramp or pain have been reported within minutes of the injection.

In clinical trials the following reactions were reported at a ≥ 1% difference in frequency from placebo: vertigo, nausea, pain in limb, dizziness, depression, dyspnoea.

Forteo® increases serum uric acid concentrations. In clinical trials, 2.8% of Forteo® patients had serum uric acid concentrations above the upper limit of normal compared with 0.7% of placebo patients. However, the hyperuricemia did not result in an increase in gout, arthralgia, or urolithiasis.

In a large clinical trial, antibodies that cross-reacted with teriparatide were detected in 2.8% of women receiving Forteo®. Generally, antibodies were first detected following 12 months of treatment and diminished after withdrawal of therapy. There was no evidence of hypersensitivity reactions, allergic reactions, effects on serum calcium, or effects on BMD response.

Overdose

Signs and symptoms
Forteo® has been administered in single doses of up to 100 micrograms and in repeated doses of up to 60 micrograms/day for 6 weeks.

The effects of overdose that might be expected include delayed hypercalcaemia and risk of orthostatic hypotension. Nausea, vomiting, dizziness, and headache can also occur.

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Overdose experience based on post-marketing spontaneous reports:
In post-marketing spontaneous reports, there have been cases of medication error where the entire contents (up to 800 mcg) of the teriparatide pen have been administered as a single dose. Transient events reported have included nausea, weakness/lethargy and hypotension. In some cases, no adverse events occurred as a result of the overdose. No fatalities associated with overdose have been reported.

Overdose management:
There is no specific antidote for Forteo®. Treatment of suspected overdose should include transitory discontinuation of Forteo®, monitoring of serum calcium, and implementation of appropriate supportive measures, such as hydration.

PHARMACOLOGICAL PROPERTIES

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

Mechanism of action:
Endogenous 84-amino-acid parathyroid hormone (PTH) is the primary regulator of calcium and phosphate metabolism in bone and kidney. Forteo® (rhPTH(1-34)) is the active fragment (1-34) of endogenous human parathyroid hormone. Physiological actions of PTH include stimulation of bone formation by direct effects on bone forming cells (osteoblasts); indirectly increasing the intestinal absorption of calcium and increasing the tubular re-absorption of calcium and excretion of phosphate by the kidney.

Pharmacodynamic effects
Forteo® is a bone formation agent to treat osteoporosis. The skeletal effects of Forteo® depend upon the pattern of systemic exposure. Once-daily administration of Forteo® increases apposition of new bone on trabecular and cortical bone surfaces by preferential stimulation of osteoblastic activity over osteoclastic activity.

Clinical efficacy
Risk Factors
Independent risk factors, for example, low BMD, age, the existence of previous fracture, family history of hip fractures, high bone turnover and low body mass index should be considered in order to identify women and men at increased risk of osteoporotic fractures who could benefit from treatment.

Premenopausal women with glucocorticoid-induced osteoporosis should be considered at high risk for fracture if they have a prevalent fracture or a combination of risk factors that place them at high risk for fracture (e.g., low bone density [e.g., T score ≤−2], sustained high dose glucocorticoid therapy [e.g., ≥7.5 mg/day for at least 6 months], high underlying disease activity, low sex steroid levels).

Postmenopausal women:
The pivotal study included 1637 postmenopausal women (mean age 69.5 years). At baseline, ninety percent of the patients had one or more vertebral fractures, and on average, vertebral BMD was 0.82 g/cm^2 (equivalent to a T-score = - 2.6). All patients were offered 1000 mg calcium per day and at least 400 IU vitamin D per day. Results from up to 24 months (median: 19 months) treatment with Forteo® demonstrate statistically significant fracture reduction (Table 2). To prevent one or more new vertebral fractures, 11 women had to be treated for a median of 19 months.

Table 2

Fracture Incidence in Postmenopausal Women			
	Placebo (N = 544) (%)	Forteo® (N = 541) (%)	Relative risk (95% CI) vs. placebo
New vertebral fracture (≥1) [a]	14.3	5.0 [b]	0.35 (0.22 , 0.55)
Multiple vertebral fractures (≥2) [a]	4.9	1.1 [b]	0.23 (0.09 ,- 0.60)
Non-vertebral fragility fractures [c]	5.5%	2.6% [d]	0.47 (0.25 , 0.87)
Major non-vertebral fragility fractures [c] (hip, radius, humerus, ribs and pelvis)	3.9%	1.5% [d]	0.38 (0.17 , 0.86)

Abbreviations: N = number of patients randomly assigned to each treatment group; CI = Confidence Interval.
[a] The incidence of vertebral fractures was assessed in 448 placebo and 444 Forteo® patients who had baseline and follow-up spine radiographs.
[b] p≤0.001 compared with placebo
[c] A significant reduction in the incidence of hip fractures has not been demonstrated
[d] p≤0.025 compared with placebo

After 19 months (median) treatment, bone mineral density (BMD) had increased in the lumbar spine and total hip, respectively, by 9% and 4% compared with placebo (p<0.001).

Post-treatment management: Following treatment with Forteo®, 1262 postmenopausal women from the pivotal trial enrolled in a post-treatment follow-up study. The primary objective of the study was to collect safety data of Forteo®. During this observational period, other osteoporosis treatments were allowed and additional assessment of vertebral fractures was performed.
During a median of 18 months following discontinuation of Forteo®, there was a 41% reduction (p=0.004) compared with placebo in the number of patients with a minimum of one new vertebral fracture.

In an open-label study, 503 postmenopausal women with severe osteoporosis and a fragility fracture within the previous 3 years (83% had received previous osteoporosis therapy) were treated with Forteo® for up to 24 months. At 24 months, the mean increase from baseline in lumbar spine, total hip and femoral neck BMD was 10.5%, 2.6% and 3.9% respectively. The mean increase in BMD from 18 to 24 months was 1.4%, 1.2%, and 1.6% at the lumbar spine, total hip, and femoral neck,respectively.

A 24-month, randomized, double-blind, comparator-controlled Phase 4 study included 1,360 postmenopausal women with established osteoporosis. 680 subjects were randomised to Forteo® and 680 subjects were randomised to oral risedronate 35 mg/week. At baseline, the women had a mean age of 72.1 years and a median of 2 prevalent vertebral fractures; 57.9% of patients had received previous bisphosphonate therapy and 18.8% took concomitant glucocorticoids during the study. 1,013 (74.5%) patients completed the 24-month follow-up. The mean (median) cumulative dose of glucocorticoid was 474.3 (66.2) mg in the teriparatide arm and 898.0 (100.0) mg in the risedronate arm. The mean (median) vitamin D intake for the teriparatide arm was 1433 IU/day (1400 IU/day) and for the risedronate arm was 1191 IU/day (900 IU/day). For those subjects who had baseline and follow-up spine radiographs, the incidence of new vertebral fractures was 28/516 (5.4%) in Forteo® - and 64/533 (12.0%) in risedronate-treated patients, relative risk (95% CI) = 0.44 (0.29-0.68), P<0.0001. The cumulative incidence of pooled clinical fractures (clinical vertebral and non vertebral fractures) was 4.8% in Forteo® and 9.8% in risedronate-treated patients, hazard ratio (95% CI) = 0.48 (0.32-0.74), P=0.0009.

Male osteoporosis:

437 patients (mean age 58.7 years) were enrolled in a clinical trial for men with hypogonadal (defined as low morning free testosterone or an elevated FSH or LH) or idiopathic osteoporosis. Baseline spinal and femoral neck bone mineral density mean T-scores were -2.2 and -2.1, respectively. At baseline, 35% of patients had a vertebral fracture and 59% had a non-vertebral fracture.

All patients were offered 1000 mg calcium per day and at least 400 IU vitamin D per day. Lumbar spine BMD significantly increased by 3 months. After 12 months, BMD had increased in the lumbar spine and total hip by 5% and 1%, respectively, compared with placebo. However, no significant effect on fracture rates was demonstrated

Glucocorticoid-induced osteoporosis:

The efficacy of Forteo® in men and women (N=428) receiving sustained systemic glucocorticoid therapy (equivalent to 5 mg or greater of prednisone for at least 3 months) was demonstrated in an 18 month primary phase of a 36-month, randomized, double-blind, comparator-controlled study (alendronate 10 mg/day). Twenty-eight percent of patients had one or more radiographic vertebral fractures at baseline. All patients were offered 1000 mg calcium per day and 800 IU vitamin D per day.

This study included postmenopausal women (N=277), premenopausal women (N=67), and men (N=83). At baseline, the postmenopausal women had a mean age of 61 years, mean lumbar spine BMD T score of −2.7, median prednisone equivalent dose of 7.5 mg/day, and 34% had one or more radiographic vertebral fractures; premenopausal women had a mean age of 37 years, mean lumbar spine BMD T score of −2.5, median prednisone equivalent dose of 10 mg/day, and 9% had one or more radiographic vertebral fractures; and men had a mean age of 57 years, mean lumbar spine BMD T score of −2.2, median prednisone equivalent dose of 10 mg/day, and 24% had one or more radiographic vertebral fractures.

Sixty-nine percent of patients completed the 18-month primary phase. At 18 month endpoint, Forteo® significantly increased lumbar spine BMD (7.2%) compared with alendronate (3.4%) (p<0.001). Forteo® increased BMD at the total hip (3.6%) compared with alendronate (2.2%) (p<0.01), as well as at the femoral neck (3.7%) compared with alendronate (2.1%) (p<0.05). In patients treated with teriparatide lumbar spine, total hip and femoral neck BMD increased between18 and 24 months by additional 1.7%, 0.9% and 0.4% respectively.

At 36 months, analysis of spinal X-rays from 169 alendronate patients and 173 Forteo patients showed that 13 patients in the alendronate group (7.7 %) had experienced a new vertebral fracture compared with 3 patients in the Forteo® group (1.7 %) (p=0.01). In addition, 15 of 214 patients in the alendronate group (7.0 %) had experienced a nonvertebral fracture compared with 16 of 214 patients in the Forteo® group (7.5 %) (p=0.84).

In premenopausal women, the increase in BMD from baseline to 18 month endpoint was significantly greater in the Forteo® group compared with the alendronate group at the lumbar spine (4.2% versus −1.9%; p<0.001) and total hip (3.8% versus 0.9%; p=0.005). However, no significant effect on fracture rates was demonstrated.

Pharmacokinetic properties:

Elimination
Forteo® is eliminated through hepatic and extra-hepatic clearance (approximately 62 L/hr in women and 94 L/hr in men).

Distribution
The volume of distribution is approximately 1.7 L/kg. The half-life of Forteo® is approximately 1 hour when administered subcutaneously, which reflects the time required for absorption from the injection site.

Biotransformation
No metabolism or excretion studies have been performed with Forteo® but the peripheral metabolism of parathyroid hormone is believed to occur predominantly in liver and kidney.

Elderly
No differences in Forteo® pharmacokinetics were detected with regard to age (range 31 to 85 years). Dosage adjustment based on age is not required.

Preclinical safety data

Teriparatide was not genotoxic in a standard battery of tests. It produced no teratogenic effects in rats, mice or rabbits. There were no important effects observed in pregnant rats or mice administered teriparatide at daily doses of 30 to 1000 mcg/kg. However, foetal resorption and reduced litter size occurred in pregnant rabbits administered daily doses of 3 to 100 mcg/kg. The embryotoxicity observed in rabbits may be related to their much greater sensitivity to the effects of PTH on blood ionised calcium compared with rodents.

Rats treated with near-life time daily injections had dose-dependent exaggerated bone formation and increased incidence of osteosarcoma most probably due to an epigenetic mechanism. Teriparatide did not increase the incidence of any other type of neoplasia in rats. Due to the differences in bone physiology in rats and humans, the clinical relevance of these findings is probably minor. No bone tumours were observed in ovariectomised monkeys treated neither for 18 months nor during a 3-year follow-up period after treatment. In addition, no osteosarcomas have been observed in clinical trials or during the post treatment follow-up study.

Animal studies have shown that severely reduced hepatic blood flow decreases exposure of PTH to the principal cleavage system (Kupffer cells) and consequently clearance of PTH(1-84).

PHARMACEUTICAL PARTICULARS

List of excipients

Glacial acetic acid
Sodium acetate (anhydrous)
Mannitol
Metacresol
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Water for injections

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf life

2 years

Chemical, physical and microbiological in-use stability has been demonstrated for 28 days at 2-8°C.

Once opened, the product may be stored for a maximum of 28 days at 2°C to 8°C. Other in-use storage times and conditions are the responsibility of the user.

Special precautions for storage

Store in a refrigerator (2°C–8°C) at all times. The pen should be returned to the refrigerator immediately after use. Do not freeze.

Do not store the injection device with the needle attached.

Nature and contents of container
2.4 mL solution in cartridge (siliconised Type I glass) with a plunger (halobutyl rubber), disc seal (polyisoprene/ bromobutyl rubber laminate)/aluminium assembled into a disposable pen.

Forteo® is available in pack sizes of 1 pen. Each pen contains 28 doses of 20 micrograms (per 80 microliters).

Special precautions for disposal

Forteo® is supplied in a pre-filled pen. Each pen should be used by only one patient. A new, sterile needle must be used for every injection. Each Forteo® pack is provided with a user manual that fully describes the use of the pen. No needles are supplied with the product. The device can be used with insulin pen injection needles. After each injection, the Forteo® pen should be returned to the refrigerator.

Forteo® should not be used if the solution is cloudy, coloured or contains particles. Please also refer to the User Manual for instructions on how to use the pen.

Any unused product or waste material should be disposed of in accordance with local requirements.

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