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EPAR summary for the public

Forsteo

teriparatide

This is a summary of the European public assessment report (EPAR) for Forsteo. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Forsteo.

What is Forsteo?

Forsteo is a medicine that contains the active substance teriparatide. It is available as a solution for injection in prefilled pens (one 2.4 ml prefilled pen contains 600 micrograms of teriparatide).

What is Forsteo used for?

Forsteo is used for the treatment of osteoporosis (a disease that makes bones fragile) in the following groups:

- women who have been through the menopause. In these patients, Forsteo has been shown to significantly reduce vertebral (spine) and non-vertebral fractures (broken bones), but not those of the hip;
- men who are at an increased risk of fractures;
- men and women who are at an increased risk of fractures due to long-term treatment with glucocorticoids (a type of steroid).

The medicine can only be obtained with a prescription.



How is Forsteo used?

The recommended dose is 20 micrograms of Forsteo given once a day as an injection under the skin of the thigh or abdomen (tummy). Patients may inject themselves once they have been trained. A user manual is available for the pen.

Patients should receive calcium and vitamin D supplements if they do not get enough from their diet. Forsteo can be used for up to two years. Only one two-year course of Forsteo should be given to a patient in their lifetime.

How does Forsteo work?

Osteoporosis happens when not enough new bone grows to replace the bone that is naturally broken down. Gradually, the bones become thin and fragile, and more likely to break. In women, osteoporosis is more common after the menopause, when the levels of the female hormone oestrogen fall. Osteoporosis can also occur in both sexes as a side effect of glucocorticoid treatment.

The active substance in Forsteo, teriparatide, is identical to part of the human parathyroid hormone. It acts like the hormone to stimulate bone formation by acting on osteoblasts (bone-forming cells). It also increases the absorption of calcium from food and prevents too much calcium being lost in the urine.

How has Forsteo been studied?

Forsteo has been studied in three main studies. The first study involved 1,637 women with osteoporosis who had been through the menopause (average age: 69.5 years), in which Forsteo was compared with placebo (a dummy treatment) for an average of 19 months. The main measure of effectiveness was the number of new vertebral fractures at the end of the study, although the study also looked at non-vertebral fractures. The patients were treated for up to 23 months.

The second study looked at the use of Forsteo in 437 men with osteoporosis, comparing its effect on the density of bones in the spine with that of placebo.

The third study compared the effects of Forsteo and alendronate (another medicine used to treat osteoporosis) on spine bone density over three years. The study included 429 women and men who had osteoporosis and had been taking glucocorticoids for at least three months.

An additional study looked at the effects of Forsteo on bone density over two years in 234 women who had been through the menopause.

What benefit has Forsteo shown during the studies?

Forsteo was more effective than placebo in reducing vertebral fractures: 5% of the women who received Forsteo had a new fracture during the study, compared with 14% in the group who received placebo. Forsteo reduced the risk of developing a new vertebral fracture over 19 months by 65% compared with placebo. It also reduced the risk of non-vertebral fractures by 62%, but did not reduce the risk of hip fractures.

In the study in men, Forsteo increased bone density in the spine by about 6% after an average of almost 12 months.

In the study of patients taking glucocorticoids, Forsteo was more effective than alendronate: after 18 months, patients receiving Forsteo had a 7% increase in bone density in the spine, compared with 3% in those receiving alendronate.

The studies also showed that the benefits of Forsteo treatment continued to increase for up to two years, with further increases in bone density.

What is the risk associated with Forsteo?

The most common side effect with Forsteo (seen in more than 1 patient in 10) is pain in the arms or legs. For the full list of all side effects reported with Forsteo, see the package leaflet.

Forsteo must not be used in patients who have other bone diseases such as Paget's disease, bone cancer or bone metastases (cancer that has spread to the bone), patients who have had radiation therapy of the skeleton, or patients who have hypercalcaemia (high blood calcium levels), unexplained high levels of alkaline phosphatase (an enzyme) or severe kidney disease. Forsteo must not be used in children or in young adults whose bones are not yet fully mature, or during pregnancy or breastfeeding. For the full list of restrictions, see the package leaflet.

Why has Forsteo been approved?

The CHMP concluded that Forsteo's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Forsteo?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Forsteo have been included in the summary of product characteristics and the package leaflet.

Other information about Forsteo

The European Commission granted a marketing authorisation valid throughout the European Union for Forsteo on 10 June 2003.

The full EPAR for Forsteo can be found on the Agency's website: ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports. For more information about treatment with Forsteo, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2016.