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Withdrawal of application for the marketing authorisation of Teriparatide Ascend (teriparatide)

Ascend GmbH withdrew its application for a marketing authorisation of Teriparatide Ascend for the treatment of osteoporosis (a disease that makes bones fragile).

The company withdrew the application on 6 May 2025.

What is Teriparatide Ascend and what was it intended to be used for?

Teriparatide Ascend was developed as a medicine for the treatment of adults with osteoporosis. It was intended for use in:

- women who have been through the menopause;
- men who are at an increased risk of fractures;
- men and women who are at increased risk of fractures due to long-term treatment with glucocorticoids (a type of steroid).

Teriparatide Ascend contains the active substance teriparatide and was to be available as a pre-filled pen for injection under the skin of the thigh or abdomen (tummy) once a day.

Teriparatide Ascend was developed as a 'biosimilar' medicine. This means that Teriparatide Ascend was intended to be highly similar to another biological medicine already authorised in the EU (the 'reference medicine'). The reference medicine for Teriparatide Ascend is Forsteo. For more information on biosimilar medicines, see here.

How does Teriparatide Ascend 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 long-term glucocorticoid treatment.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The active substance in Teriparatide Ascend, 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.

What did the company present to support its application?

The company presented results from laboratory studies intended to show that the active substance in Teriparatide Ascend is highly similar to that in Forsteo in terms of structure, purity and biological activity. They also presented results from a study that looked at whether Teriparatide Ascend was bioequivalent to Forsteo. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

Because Teriparatide Ascend was developed as a biosimilar medicine, the studies on the effectiveness of teriparatide carried out with Forsteo did not all need to be repeated for Teriparatide Ascend.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company. After the Agency had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the data and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Teriparatide Ascend could not have been authorised for the treatment of osteoporosis.

The Agency's main concern related to the way the bioequivalence study had been carried out. The study did not allow accurate measurements of the active substance in the body. A number of people already had measurable concentrations of the active substance in their blood before the start of the study, which affected the reliability of the study results. Therefore, at the time of the withdrawal, the Agency's opinion was that the bioequivalence of Teriparatide Ascend to Forsteo could not be established.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that its withdrawal was based on a major issue with the bioequivalence assay.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no ongoing clinical trials with Teriparatide Ascend.