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

CinnaGen Co. Unipessoal Lda withdrew its application for a marketing authorisation of Teriparatide Cinnagen for the treatment of osteoporosis in adults.

The company withdrew the application on 9 September 2021.

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

Teriparatide Cinnagen was developed as a medicine to treat osteoporosis, a condition in which bones become fragile and prone to fractures, in:

- women who have been through the menopause;
- 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).

Teriparatide Cinnagen contains the active substance teriparatide and was to be available in pre-filled pens for injection under the skin.

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

How does Teriparatide Cinnagen work?

The active substance in Teriparatide Cinnagen, teriparatide, is identical to part of the human parathyroid hormone (PTH). 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.

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What did the company present to support its application?

The company provided results from laboratory studies comparing Teriparatide Cinnagen with Forsteo to show that the active substance in Teriparatide Cinnagen is highly similar to that in Forsteo in terms of structure and biological activity.

The company also presented the results of a study involving 60 healthy women to investigate whether Teriparatide Cinnagen was distributed in the same way in the body as the reference medicine Forsteo and had similar effects.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company. The company had not responded to the questions at the time of the withdrawal.

What did the Agency recommend at that time?

Based on the review of the data, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Teriparatide Cinnagen could not have been authorised for the treatment of osteoporosis.

The Agency had several concerns about the quality of the medicine, including the nature of any impurities, and the way it was produced. Documentation was not always clear, making it hard to draw conclusions. There were also uncertainties about the way results from the study on distribution in the body had been analysed, and about the intention to use a pen that could deliver different doses from the one authorised, which might confuse patients.

Overall, at the time of the withdrawal these concerns made it impossible to conclude that Teriparatide Cinnagen was highly similar to Forsteo and would behave in the same way in its authorised uses, with comparable benefits and risks.

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 they withdrew their application following feedback about EMA's concerns and their estimate that these could not be addressed in the time available.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Teriparatide Cinnagen.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.