



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Update of 27 April 2018:

The applicant for Eladynos has requested a re-examination of the CHMP's March 2018 opinion. Upon receipt of the grounds of the request, the CHMP will re-examine its opinion and issue a final recommendation.

23 March 2018

Refusal of the marketing authorisation for Eladynos (abaloparatide)

On 22 March 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Eladynos, intended for the treatment of osteoporosis (a disease that makes bones fragile).

The company that applied for authorisation is Radius International Ltd. It may request a re-examination of the opinion within 15 days of receipt of notification of this negative opinion.

What is Eladynos?

Eladynos is a medicine that contains the active substance abaloparatide. It was to be available as a solution for injection under the skin.

What was Eladynos expected to be used for?

Eladynos was expected to be used to treat osteoporosis. It was to be used in women who have been through the menopause and who are at risk of bone fractures, a complication of osteoporosis.

How is Eladynos expected to 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 fracture. In women,

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osteoporosis is more common after the menopause, when the levels of the female hormone oestrogen fall.

The active substance in Eladynos, abaloparatide, is similar to part of the human parathyroid hormone. It stimulates bone formation by acting on osteoblasts (bone-forming cells).

What did the company present to support its application?

The company presented the results of one main study in women who had been through the menopause and who were at risk of fractures. Women received Eladynos or teriparatide (another medicine used to treat osteoporosis) or placebo (a dummy treatment) for 18 months. Measures of effectiveness were the number of new vertebral fractures and the number of non-vertebral fractures (including hip fractures, which can be serious and disabling).

What were the CHMP's main concerns that led to the refusal?

The CHMP considered that the main study did not satisfactorily show that Eladynos is effective at preventing non-vertebral fractures in women who have been through the menopause.

The data from two of the study sites were not reliable and had to be excluded as the study had not been conducted in compliance with 'good clinical practice' (GCP) at those sites.

From a safety point of view, the CHMP was concerned about the medicine's effects on the heart, such as increases in heart rate and palpitations.

Because most post-menopausal women are at an increased risk of heart problems, the CHMP could not identify a group of patients in whom the benefits would outweigh the risks. Therefore, the committee recommended that the medicine be refused marketing authorisation.

What consequences does this refusal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that there are no consequences for patients currently included in clinical trials with Eladynos.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.