EMA/852056/2022
EMEA/H/C/005928

Eladynos (*abaloparatide*)

An overview of Eladynos and why it is authorised in the EU

What is Eladynos and what is it used for?

Eladynos is a medicine used to treat osteoporosis (a disease that makes bones fragile) in women who have been through menopause and are at increased risk of bone fractures.

This medicine contains the active substance abaloparatide.

How is Eladynos used?

Eladynos is given once daily as an injection under the skin of the lower abdomen (belly). The maximum duration of treatment with Eladynos is 18 months. Patients or their carers can inject Eladynos themselves once they have been trained to do so.

During treatment with Eladynos, the patient should take calcium and vitamin D supplements if they are not getting enough from their diet.

The medicine can only be obtained with a prescription. For more information about Eladynos, see the package leaflet or contact your doctor or pharmacist.

How does Eladynos 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 (break). In women, osteoporosis is more common after the menopause, when levels of the female hormone oestrogen fall.

The active substance in Eladynos, abaloparatide, is similar to part of the human parathyroid hormone. It acts like this hormone in stimulating bone formation by activating bone-forming cells called osteoblasts.

What benefits of Eladynos have been shown in studies?

In a main study involving 2,070 patients, Eladynos was more effective than placebo (a dummy treatment) in reducing fractures in the spine in women with osteoporosis who have been through menopause.

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After 18 months, 0.5% of those treated with Eladynos had a new spinal fracture compared with 4.2% in the group who received placebo.

What are the risks associated with Eladynos?

The most common side effects with Eladynos (which may affect more than 1 in 10 people) are hypercalciuria (high calcium levels in the urine) and dizziness. Other common side effects (which may affect up to 1 in 10 people) are back pain, nausea, headache, joint pain, high blood pressure, reactions at the injection site, and palpitations (a forceful heartbeat that may be rapid or irregular). For the full list of side effects of Eladynos, see the package leaflet.

Eladynos must not be used in women who are hypersensitive (allergic) to abaloparatide or any of the other ingredients, pregnant or breastfeeding women, women who are able to have children and women with hypercalcaemia (high calcium levels in the blood), severely reduced kidney function or unexplained high levels of alkaline phosphatase (an enzyme). Eladynos must also not be used in patients at risk for osteosarcoma (a type of bone cancer) or in patients who have bone cancer or cancer that has spread to the bones.

For the full list of restrictions, see the package leaflet.

Why is Eladynos authorised in the EU?

There is a need for new safe and effective medicines for preventing fractures in women who have been through menopause and have osteoporosis. The main study showed that Eladynos reduces the risk of spinal fractures in these patients. The results also suggest that it may reduce the risk of non-spinal fractures.

Regarding safety, the side effects of Eladynos were mostly mild to moderate. Although Eladynos can increase the heart rate after injection, there is no evidence that it causes major heart problems. As a precaution, doctors should assess the risks before starting treatment and should monitor the heart function of patients with cardiovascular disease (affecting the heart and blood circulation).

The European Medicines Agency decided that Eladynos' benefits are greater than its risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Eladynos are continuously monitored. Suspected side effects reported with Eladynos are carefully evaluated and any necessary action taken to protect patients.

Other information about Eladynos

Eladynos received a marketing authorisation valid throughout the EU on 12 December 2022.

Further information on Eladynos can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/eladynos

This overview was last updated in 12-2022.