EMA/329164/2025
EMEA/H/C/006490

Kefdensis *(denosumab)*

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

What is Kefdensis and what is it used for?

Kefdensis is a medicine used to treat the following conditions:

- osteoporosis (a disease that makes bones fragile) in women who have been through the menopause and in men who have an increased risk of fracture (broken bones). In women who have been through the menopause Kefdensis reduces the risk of fractures in the spine and elsewhere in the body, including in the hip;
- bone loss in men receiving treatment for prostate cancer that increases their risk of fractures; Kefdensis reduces the risk of fractures in the spine;
- bone loss in adults at increased risk of fractures who are treated long term with corticosteroid medicines given by mouth or injection.

The medicine contains the active substance denosumab and is a biological medicine. It is a 'biosimilar medicine'; this means that Kefdensis is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Kefdensis is Prolia. For more information on biosimilar medicines, see here.

How is Kefdensis used?

Kefdensis is available as a solution for injection in prefilled syringes.

Kefdensis is given once every 6 months as an injection under the skin in the thigh, abdomen (belly) or back of the arm. During treatment with Kefdensis, the doctor should ensure that the patient is receiving calcium and vitamin D supplements. Kefdensis can be given by someone who has been trained in how to give injections appropriately.

The medicine can only be obtained with a prescription.

For more information about using Kefdensis, see the package leaflet or contact your doctor or pharmacist.

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How does Kefdensis work?

The active substance in Kefdensis, denosumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a specific structure in the body called RANKL. RANKL is involved in activating osteoclasts, the cells in the body that are involved in breaking down bone tissue. By attaching to and blocking RANKL, denosumab reduces the formation and activity of the osteoclasts. This reduces the loss of bone and maintains bone strength, making fractures less likely to happen.

What benefits of Kefdensis have been shown in studies?

Laboratory studies comparing Kefdensis with Prolia have shown that the active substance in Kefdensis is highly similar to that in Prolia in terms of structure, purity and biological activity. Studies have also shown that giving Kefdensis produces similar levels of the active substance in the body to those seen with Prolia.

In addition, a study involving 532 women with osteoporosis who have been through the menopause compared the effectiveness of Kefdensis with that of Prolia. After one year of treatment, bone mineral density in the spine (a measure of how strong the bones are) increased by around 5.3% in women who received Kefdensis and 5.2% in those who received Prolia.

Because Kefdensis is a biosimilar medicine, the studies on the effectiveness of denosumab carried out with Prolia do not all need to be repeated for Kefdensis.

What are the risks associated with Kefdensis?

The safety of Kefdensis has been evaluated and, on the basis of all the studies carried out, the side effects of the medicine are considered to be comparable to those of the reference medicine Prolia.

For the complete list of side effects and restrictions of Kefdensis, see the package leaflet.

The most common side effects with Kefdensis (which may affect more than 1 in 10 people) include pain in the arms or legs, and bone, joint and muscle pain. Uncommon side effects (which may affect up to 1 in 100 people) include cellulitis (inflammation of deep skin tissue). Rare side effects (which may affect up to 1 in 1,000 people) include hypocalcaemia (low blood calcium), hypersensitivity (allergy), osteonecrosis of the jaw (damage to the bones of the jaw, which could lead to pain, sores in the mouth or loosening of teeth) and unusual fractures of the thigh bone.

Kefdensis must not be used in people with hypocalcaemia (low blood calcium levels).

Why is Kefdensis authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Kefdensis has a highly similar structure, purity and biological activity to Prolia and is distributed in the body in the same way. In addition, a study has shown that Kefdensis and Prolia are equivalent in terms of safety and effectiveness in women with osteoporosis who have been through the menopause.

All these data were considered sufficient to conclude that Kefdensis will have the same effects as Prolia in its authorised uses. Therefore, the Agency’s view was that, as for Prolia, the benefits of Kefdensis outweigh the identified risks and it can be authorised for use in the EU.

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

The company that markets Kefdensis will provide a card to inform patients about the risk of osteonecrosis of the jaw and to instruct them to contact their doctor if they experience symptoms.

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

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

Other information about Kefdensis

Kefdensis received a marketing authorisation valid throughout the EU on 17 November 2025.

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

This overview was last updated in 11-2025.