EMA/542970/2024
EMEA/H/C/006424

Obodence (*denosumab*)

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

What is Obodence and what is it used for?

Obodence 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 fractures (broken bones). In women who have been through the menopause, Obodence reduces the risk of fractures in the spine and elsewhere in the body, including the hips;
- bone loss in men receiving treatment for prostate cancer that increases their risk of fractures. Obodence reduces the risk of fractures in the spine;
- bone loss in adults at increased risk of fractures due to long term treatment with corticosteroid medicines given by mouth or injection.

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

How is Obodence used?

The medicine can only be obtained with a prescription. Obodence is available as a solution for injection in prefilled syringes.

Obodence 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 Obodence, the doctor should ensure that the patient is receiving calcium and vitamin D supplements. Obodence can be given by someone who has been trained in how to give injections appropriately.

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

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How does Obodence work?

The active substance in Obodence, denosumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a specific protein 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 osteoclasts. This reduces bone loss and maintains bone strength, making fractures less likely to happen.

What benefits of Obodence have been shown in studies?

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

In addition, a study involving 457 women with osteoporosis who have been through the menopause compared the effectiveness of Obodence with that of Prolia. After a year of treatment, bone mineral density (a measure of how strong the bones are) in the spine increased by around 5.7% women who received Obodence and 5.3% in those who received Prolia.

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

What are the risks associated with Obodence?

The safety of Obodence 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 Obodence, see the package leaflet.

The most common side effects with Obodence (which may affect more than 1 in 10 people) include hypocalcaemia (low levels of calcium in the blood) and musculoskeletal pain (pain in the muscles and bones). Other common side effects (which may affect up to 1 in 10 people) include osteonecrosis in the jaw (damage to the bones of the jaw, which could lead to pain, sores in the mouth and loose teeth), hypersensitivity (allergic reactions) and fractures.

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

Why is Obodence authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Obodence has a highly similar structure, purity and biological activity to Prolia and is distributed in the body in the same way. In addition, studies in postmenopausal osteoporosis have shown that Obodence and Prolia are equivalent in terms of safety and effectiveness in this condition.

All these data were considered sufficient to conclude that Obodence will have the same effects as Prolia in its authorised uses. Therefore, the Agency’s view was that, as for Prolia, the benefits of Obodence 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 Obodence?

The company that markets Obodence 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 Obodence have been included in the summary of product characteristics and the package leaflet.

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

Other information about Obodence

Obodence received a marketing authorisation valid throughout the EU on 12 February 2025.

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

This overview was last updated in 02-2025.