EMA/316727/2025
EMEA/H/C/006239

Degevma (*denosumab*)

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

What is Degevma and what is it used for?

Degevma is a medicine used to prevent bone complications in adults with advanced cancer that has spread to the bone. These complications include fractures (breaks in the bone), spinal compression (pressure on the spinal cord caused by damage to the surrounding bone) or bone problems requiring radiotherapy (treatment with radiation) or surgery.

Degevma is also used to treat a type of bone cancer called giant cell tumour of bone in adults and adolescents whose bones have fully developed. It is used in patients who cannot be treated by surgery or in whom surgery is likely to cause complications.

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

How is Degevma used?

Degevma can only be obtained with a prescription. It is available as a solution for injection to be given under the skin in the thigh, abdomen (belly) or upper arm.

To prevent bone complications in cancer that has spread to the bone, the medicine is given once every 4 weeks. In patients with giant cell tumour of bone, it is given once every 4 weeks, with an additional dose given 1 week and 2 weeks after the first dose.

Patients should take calcium and vitamin D supplements while being treated with Degevma.

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

How does Degevma work?

The active substance in Degevma, denosumab, is a monoclonal antibody which has been designed to recognise and attach to a protein called RANKL. This protein activates osteoclasts, the cells in the body that are involved in breaking down bone tissue. By attaching to RANKL and blocking it, denosumab

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

reduces the formation and activity of the osteoclasts. This reduces the loss of bone, making fractures and other serious bone complications less likely. RANKL is also involved in activating the osteoclast-like cells in giant cell tumours of bone. Treatment with denosumab therefore prevents them from growing and breaking down bone, allowing normal bone to replace the tumour.

What benefits of Degevma have been shown in studies?

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

In addition, a study compared the effectiveness of the denosumab in Degevma with that of an authorised medicine containing denosumab in 332 women with osteoporosis (a disease that makes bones fragile) who have been through the menopause. After a year of treatment, bone mineral density in the spine (a measure of how strong the bones are) increased by 4.8% in women who received Degevma and 4.5% in those who received the other denosumab medicine.

Because denosumab works in a similar way in osteoporosis and in the conditions Degevma is intended to treat, a specific study on the effectiveness of Degevma in these conditions is not needed.

What are the risks associated with Degevma?

The safety of Degevma 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 Xgeva.

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

The most common side effects with Degevma (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).

Hypocalcaemia mostly occurs within the first 2 weeks of starting treatment and can be severe; however, it can be managed with calcium and vitamin D supplementation.

Degevma must not be used in patients with wounds from dental or mouth surgery that have not yet healed, or in people with severe, untreated hypocalcaemia.

Why is Degevma authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Degevma has a highly similar structure, purity and biological activity to Xgeva and is distributed in the body in the same way. In addition, a study has shown that Degevma is as effective as another denosumab-containing medicine in women with osteoporosis. Denosumab works in a similar way in the treatment of osteoporosis and in Degevma’s intended uses.

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

The company that markets Degevma 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 have symptoms.

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

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

Other information about Degevma

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

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

This overview was last updated in 12-2025.