



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Enwylma (*denosumab*)

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

What is Enwylma and what is it used for?

Enwylma 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.

Enwylma 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.

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

How is Enwylma used?

Enwylma can only be obtained with a prescription. It is available as a solution for injection under the skin in the thigh, belly or upper arm.

To prevent bone complications in cancer that has spread to the bone, the medicine is given once every 4 weeks as a single injection under the skin. In patients with giant cell tumour of bone, it is injected under the skin once a week for 3 weeks, and then once every 4 weeks.

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

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

How does Enwylma work?

The active substance in Enwylma, 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

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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 tumour of bone. Treatment with denosumab therefore prevents them from growing and breaking down bone, allowing normal bone to replace the tumour.

What benefits of Enwylma have been shown in studies?

Laboratory studies comparing Enwylma with Xgeva have shown that the active substance in Enwylma is highly similar to that in Xgeva in terms of structure, purity and biological activity. Studies have also shown that giving Enwylma 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 Enwylma with that of another medicine containing denosumab in 558 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 around 5.5 % in both women who received Enwylma and those who received the other denosumab medicine.

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

What are the risks associated with Enwylma?

The safety of Enwylma has been evaluated and, based on 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 Enwylma, see the package leaflet.

The most common side effects with Enwylma (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.

Enwylma 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 Enwylma authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Enwylma 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 Enwylma 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 Enwylma's intended uses.

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

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

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

Other information about Enwylma

Enwylma received a marketing authorisation valid throughout the EU on 26 June 2025.

Further information on Enwylma can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/enwylma.

This overview was last updated in 11-2025.