



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Denosumab Ascend (*denosumab*)

A plain-language overview of Denosumab Ascend and why it is authorised in the EU

What is Denosumab Ascend and what is it used for?

Denosumab Ascend 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.

Denosumab Ascend 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.

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

How is Denosumab Ascend used?

Denosumab Ascend 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 Denosumab Ascend.

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

How does Denosumab Ascend work?

The active substance in Denosumab Ascend, denosumab, is a monoclonal antibody which has been designed to recognise and attach to a protein called RANKL. This protein activates osteoclasts, the cells

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in the body that are involved in breaking down bone tissue. By attaching to RANKL and blocking it, denosumab 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 Denosumab Ascend have been shown in studies?

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

In addition, a study compared the effectiveness of denosumab in Denosumab Ascend with that of denosumab in another medicine in 504 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 5.4% in women who received Denosumab Ascend and by 5.5% in those who received the other denosumab-containing medicine.

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

Studies carried out with Denosumab Ascend are described in more detail in the medicine's assessment report.

What are the side effects and restrictions associated with Denosumab Ascend?

The safety of Denosumab Ascend 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 Xgeva.

For the full list of side effects and restrictions of Denosumab Ascend, see the package leaflet.

The most common side effects with Denosumab Ascend (which may affect more than 1 in 10 people) are musculoskeletal pain (pain in the muscles and bones), shortness of breath and diarrhoea.

Other common side effects (which may affect up to 1 in 10 people) include hypophosphataemia (low levels of phosphates in the blood), removal of a tooth and hyperhidrosis (excessive sweating). Another common side effect in patients with advanced cancer is the development of another form of cancer.

Denosumab Ascend 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.

For the full list of side effects and restrictions with Denosumab Ascend, see the package leaflet.

Why is Denosumab Ascend authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Denosumab Ascend 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 Denosumab Ascend is as effective as another denosumab-containing medicine in the treatment of osteoporosis. Denosumab works in a similar way in the treatment of osteoporosis and in Denosumab Ascend's intended uses.

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

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

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

Other information about Denosumab Ascend

Denosumab Ascend received a marketing authorisation valid throughout the EU on 28 August 2026.

Further information on Denosumab Ascend, including the package leaflet and assessment report, can be found on the Agency's website: www.ema.europa.eu/en/medicines/human/EPAR/denosumab-ascend.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 09-2026.