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# Bildyos (*denosumab*)

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

## What is Bildyos and what is it used for?

Bildyos 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, Bildyos 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. Bildyos 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.

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

## How is Bildyos used?

Bildyos can only be obtained with a prescription and is available as a solution for injection in vials and prefilled syringes.

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

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

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## How does Bildyos work?

The active substance in Bildyos, denosumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a protein 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 Bildyos have been shown in studies?

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

In addition, a study involving 514 women with osteoporosis who have been through the menopause compared the effectiveness of Bildyos with that of Prolia. After a year of treatment, bone mineral density in the spine (a measure of how strong the bones are) increased by around 6.1% in women who received Bildyos and 6.0% in those who received Prolia.

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

## What are the risks associated with Bildyos?

The safety of Bildyos 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 with Bildyos, see the package leaflet.

The most common side effects with Bildyos (which may affect more than 1 in 10 people) include pain in the arms or legs, and bone, joint and muscle pain. Other side effects (which may affect up to 1 in 100 people) include cellulitis (inflammation of deep skin tissue). Hypocalcaemia (low blood calcium levels), hypersensitivity (allergic reactions), osteonecrosis in the jaw (damage to the bones of the jaw, which could lead to pain, sores in the mouth and loose teeth) and unusual fractures of the thigh bone may affect up to 1 in 1,000 people taking this medicine.

Bildyos must not be used in people with hypocalcaemia.

## Why is Bildyos authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Bildyos 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 Bildyos 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 Bildyos will have the same effects as Prolia in its authorised uses. Therefore, the Agency’s view was that, as for Prolia, the benefits of Bildyos 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 Bildyos?

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

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

## Other information about Bildyos

Bildyos received a marketing authorisation valid throughout the EU on 17 September 2025.

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

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