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Zadenvi (*denosumab*)

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

What is Zadenvi and what is it used for?

Zadenvi 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 fracture (broken bones). In women who have been through the menopause Zadenvi reduces the risk of fractures in the spine and elsewhere in the body, including the hip;
- bone loss in men receiving treatment for prostate cancer that increases their risk of fracture. Zadenvi 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.

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

How is Zadenvi used?

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

Zadenvi is given once every 6 months as a 60 mg injection under the skin in the thigh, abdomen (belly) or back of the arm. During treatment with Zadenvi, the doctor should ensure that the patient is receiving calcium and vitamin D supplements. Zadenvi can be given by someone who has been trained in how to give injections appropriately.

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

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How does Zadenvi work?

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

What benefits of Zadenvi have been shown in studies?

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

In addition, a study involving 558 women with osteoporosis who have been through the menopause compared the effectiveness of Zadenvi 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 5.5% in women who received Zadenvi and 5.3% in those who received Prolia.

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

What are the risks associated with Zadenvi?

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

The safety of Zadenvi 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

The most common side effects with Izamby (which may affect more than 1 in 10 people) include pain in the arms or legs, and bone, joint and muscle pain. Uncommon or rare side effects (which may affect up to 1 in 1000 people) include cellulitis (inflammation of deep skin tissue), hypocalcaemia (low blood calcium), hypersensitivity (allergy), osteonecrosis of the jaw (damage to the bones of the jaw, which could lead to pain, sores in the mouth or loosening of teeth) and unusual fractures of the thigh bone.

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

Why is Zadenvi authorised in the EU?

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

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

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

Other information about Zadenvi

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

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

This overview was last updated in 08-2025.