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Osvyrti (*denosumab*)

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

What is Osvyrti and what is it used for?

Osvyrti is a medicine used to treat:

- 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, Osvyrti reduces the risk of fractures in the spine and elsewhere in the body, including in the hip;
- bone loss in men receiving treatment for prostate cancer that increases their risk of fractures. Osvyrti reduces the risk of fractures in the spine;
- bone loss in adults at increased risk of fractures due to long term treatment with corticosteroid medicines given by mouth or injection.

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

How is Osvyrti used?

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

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

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

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

How does Osvyrti work?

The active substance in Osvyrti, 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 Osvyrti have been shown in studies?

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

In addition, a study in 522 women with osteoporosis who have been through the menopause compared the effectiveness of Osvyrti with that of Prolia. After a year of treatment, bone mineral density (a measure of how strong the bones are) in the spine increased by around 6% in both women who received Osvyrti and those who received Prolia.

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

What are the risks associated with Osvyrti?

The safety of Osvyrti 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 of Osvyrti, see the package leaflet.

Some side effects can be serious. The most frequent (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 cases of 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 have been seen in patients taking denusomab.

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

Why is Osvyrti authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Osvyrti 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 in women with osteoporosis has shown that Osvyrti and Prolia are equivalent in terms of safety and effectiveness in treating this condition.

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

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

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

Other information about Osvyrti

Osvyrti received a marketing authorisation valid throughout the EU on 26 May 2025.

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

This overview was last updated in 04-2025.