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## Rolcya (*denosumab*)

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

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

Rolcya 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, Rolcya 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 fracture. Rolcya 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.

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

### How is Rolcya used?

Rolcya can only be obtained with a prescription and is available as a solution for injection in 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 Rolcya, the doctor should ensure that the patient is receiving calcium and vitamin D supplements. Rolcya can be given by someone who has been trained in how to give injections appropriately.

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

### How does Rolcya work?

The active substance in Rolcya, 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

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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 Rolcya have been shown in studies?**

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

In addition, a study involving 527 women with osteoporosis who have been through the menopause compared the effectiveness of Rolcya 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 5.0% in women who received Rolcya and 5.1% in those who received Prolia.

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

## **What are the risks associated with Rolcya?**

The safety of Rolcya 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 Rolcya, see the package leaflet.

The most common side effects with Rolcya (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 the medicine.

Rolcya must not be used in people with hypocalcaemia.

## **Why is Rolcya authorised in the EU?**

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

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

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

### **Other information about Rolcya**

Rolcya received a marketing authorisation valid throughout the EU on 17 July 2025.

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

[ema.europa.eu/medicines/human/EPAR/Rolcya](https://ema.europa.eu/medicines/human/EPAR/Rolcya)

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