EMA/329163/2025
EMEA/H/C/006238

Ponlimsi *(denosumab)*

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

What is Ponlimsi and what is it used for?

Ponlimsi 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 Ponlimsi 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; Ponlimsi 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.

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

How is Ponlimsi used?

Ponlimsi is available as a solution for injection in prefilled syringes.

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

The medicine can only be obtained with a prescription.

For more information about using Ponlimsi, 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 Ponlimsi work?

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

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

In addition, a study compared the effectiveness of the denosumab in Ponlimsi with that Prolia in 332 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 4.8% in women who received Ponlimsi and 4.5% in those who received Prolia.

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

What are the risks associated with Ponlimsi?

The safety of Ponlimsi 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 Ponlimsi, see the package leaflet.

The most common side effects with Ponlimsi (which may affect more than 1 in 10 people) include pain in the arms or legs, and bone, joint and muscle pain. Uncommon side effects (which may affect up to 1 in 100 people) include cellulitis (inflammation of deep skin tissue). Rare side effects (which may affect up to 1 in 1,000 people) include 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.

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

Why is Ponlimsi authorised in the EU?

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

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

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

Other information about Ponlimsi

Ponlimsi received a marketing authorisation valid throughout the EU on 17 November 2025.

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

This overview was last updated in 12-2025.