EMA/376945/2018
EMEA/H/C/001120

Prolia (*denosumab*)

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

What is Prolia and what is it used for?

Prolia 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 Prolia 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 fracture. Prolia 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.

How is Prolia used?

Prolia is available as a solution for injection in prefilled syringes, each containing 60 mg denosumab.

Prolia 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 Prolia, the doctor should ensure that the patient is receiving calcium and vitamin D supplements. Prolia 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 Prolia, see the package leaflet or contact your doctor or pharmacist.

How does Prolia work?

The active substance in Prolia, 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

What benefits of Prolia have been shown in studies?

Osteoporosis in women

Prolia has been shown to be more effective than placebo (a dummy treatment) at reducing fractures in two main studies involving a total of over 8,000 women with osteoporosis who had been through the menopause. In the first of these studies, 2% of the women receiving Prolia had a new spine fracture after 3 years of treatment compared with 7% of the women receiving placebo. Prolia was also more effective at reducing the number of women who had fractures elsewhere in the body, including in the hip.

In the second study, the women were receiving treatment for breast cancer and were considered to be at high risk of fracture. Women who took Prolia had higher bone density (a measure of how strong the bones are) in the lumbar (lower) spine after 1 year of treatment than women on placebo.

Osteoporosis in men

Prolia has been compared with placebo in one main study involving 242 men with osteoporosis. In men who took Prolia bone density increased by 5.7% after 1 year of treatment compared with a 0.9% increase in men who took placebo.

Bone loss in men receiving treatment for prostate cancer

Prolia has been shown to be more effective than placebo at treating bone loss in one main study involving 1,468 men receiving treatment for prostate cancer who were at an increased risk of fracture. After 2 years, men who received Prolia had an increase in bone density in the lumbar spine that was 7% higher than in those who received placebo. In addition, after 3 years the risk of new spine fractures was lower in patients who received Prolia.

Bone loss in adults receiving long-term corticosteroid therapy

Prolia has been shown to be more effective than risedronate (a bisphosphonate medicine) at increasing bone density in one main study involving 795 adults treated with corticosteroid medicines. In patients who had been treated with corticosteroids for up to 3 months before the study, bone density in the lumbar spine increased by 3.1% after 1 year of treatment with Prolia compared with a 0.8% increase with risedronate. In patients who had been treated with corticosteroids for more than 3 months before the study, lumbar spine bone density increased by 3.6% after 1 year of treatment with Prolia compared with a 2.0% increase with risedronate.

What are the risks associated with Prolia?

The most common side effects with Prolia (seen in more than 1 patient in 10) are 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 Prolia.

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

For the full list of side effects and restrictions with Prolia, see the package leaflet.

Why is Prolia authorised in the EU?

The European Medicines Agency decided that Prolia's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Prolia?

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

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

Other information about Prolia

Prolia received a marketing authorisation valid throughout the EU on 26 May 2010.

Further information on Prolia can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

This overview was last updated in 06-2018.