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EPAR summary for the public

Prolia

denosumab

This document is a summary of the European Public Assessment Report (EPAR) for Prolia. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Prolia.

What is Prolia?

Prolia is a solution for injection that contains the active substance denosumab. It is available in prefilled syringes or in vials, each of which contains 60 mg denosumab.

What is Prolia used for?

Prolia is 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 Prolia reduces the risk of fractures in the spine and elsewhere in the body, including in the hip.

Prolia is also used to treat bone loss in men receiving treatment for prostate cancer that increases their risk of fracture. Prolia reduces the risk of fractures in the spine.

The medicine can only be obtained with a prescription.

How is Prolia used?

Prolia is given once every six months as a 60 mg injection under the skin in the thigh, abdomen (tummy) 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.

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How does Prolia work?

The active substance in Prolia, denosumab, is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen) in the body. Denosumab has been designed to attach to an antigen called RANKL, which 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.

How has Prolia been studied?

For the treatment of osteoporosis in women, Prolia has been compared with placebo (a dummy treatment) 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, the main measure of effectiveness was the number of women who had new fractures of the spine over three years. The study also looked at 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. The main measure of effectiveness was the change in bone density (a measure of how strong the bones are) in the lumbar (lower) spine after a year of treatment.

For the treatment of osteoporosis in men, Prolia has been compared with placebo in one main study involving 242 men with osteoporosis. The main measure of effectiveness was the change in bone density in the lumbar spine after a year of treatment.

For the treatment of bone loss in men receiving treatment for prostate cancer, Prolia has also been compared with placebo in one main study involving 1,468 men receiving treatment for prostate cancer who were at an increased risk of fracture. The main measure of effectiveness was the change in bone density of the lumbar spine after two years. This study also looked at the number of patients who had spine fractures over three years.

What benefit has Prolia shown during the studies?

In women with osteoporosis who had been through the menopause, Prolia was more effective than placebo at reducing fractures. After three years, 2% of the women receiving Prolia had had a new spine fracture after three years 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.

Women with breast cancer who took Prolia also had higher bone density in the lower spine after one year.

In men with osteoporosis who took Prolia bone density increased by 5.7 % after one year of treatment compared with a 0.9 % increase in men who took placebo.

In men receiving treatment for prostate cancer, Prolia was more effective than placebo at treating bone loss. After two 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 three years the risk of new spine fractures was lower in patients who received Prolia.

What is the risk 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/or 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 all side effects and restrictions with Prolia, see the package leaflet.

Why has Prolia been approved?

The CHMP decided that Prolia's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Prolia is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Prolia, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, 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.

Other information about Prolia

The European Commission granted a marketing authorisation valid throughout the European Union for Prolia on 26 May 2010.

The full EPAR for Prolia can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Prolia, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2015.