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EPAR summary for the public

Preotact

parathyroid hormone

This is a summary of the European public assessment report (EPAR) for Preotact. 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 Preotact.

What is Preotact?

Preotact is a medicine that contains the active substance parathyroid hormone. It is available as a powder and solvent, contained within a cartridge, to be made up into a solution for injection using a special injection pen. It is also available as a pre-filled pen incorporating the cartridge containing the powder and solvent Each cartridge contains 14 doses.

What is Preotact used for?

Preotact is used for the treatment of osteoporosis (a disease that makes bones fragile) in postmenopausal women who are at high risk of fractures. Preotact has been shown to significantly reduce vertebral (spine) fractures, but not hip fractures.

The medicine can only be obtained with a prescription.

How is Preotact used?

The recommended dose of Preotact is 100 micrograms, given once a day as an injection under the skin into the abdomen. When the cartridge is inserted in the special injection pen and the pen screwed together, or when the pre-filled pen is prepared for use, the powder and solvent mix to make up the solution for injection. Patients may inject themselves once they have been trained (a user manual is supplied).

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Patients may also need to take calcium and vitamin D supplements if they do not have enough from their diet. Preotact can be used for up to 24 months, after which patients can be treated with a bisphosphonate (a medicine that reduces bone loss).

How does Preotact work?

Osteoporosis happens when not enough new bone grows to replace the bone that is naturally broken down. Gradually, the bones become thin and fragile, and more likely to break (fracture). Osteoporosis is more common in women after the menopause, when the levels of the female hormone oestrogen fall.

Preotact contains parathyroid hormone, which stimulates bone formation by acting on osteoblasts (bone forming cells). It also increases the absorption of calcium from food and prevents too much calcium from being lost in the urine. The parathyroid hormone in Preotact is identical to the human parathyroid hormone. It is produced by a method known as 'recombinant DNA technology': the hormone is made by a bacterium that has received a gene (DNA) that makes it able to produce it.

How has Preotact been studied?

Preotact has been studied in one main study involving 2,532 women with postmenopausal osteoporosis. Preotact was compared with placebo (a dummy treatment). The main measure of effectiveness was the rate of vertebral fractures after 18 months of treatment. About two-thirds of the women continued taking Preotact for up to two years, and their bone density was measured. The bone density was also the main measure in another study, which looked at the use of Preotact with or without alendronate (a bisphosphonate).

What benefit has Preotact shown during the studies?

Preotact significantly reduced the risk of having a vertebral fracture, in comparison with placebo: after 18 months, there were 42 vertebral fractures in the placebo group (3.37%) and 17 in the Preotact group (1.32%). The risk reduction was higher in women who already had a fractured vertebra in the past, and in women whose score for spine bone density was already low at the start of the study, indicating that they had a more fragile spine. Increases in bone density were also seen during the study. The study of Preotact with alendronate showed that using alendronate after Preotact can bring further increases in bone density.

What is the risk associated with Preotact?

The most common side effects with Preotact (seen in more than 1 patient in 10) are hypercalcaemia (high blood calcium levels), hypercalciuria (high calcium levels in the urine) and nausea (feeling sick). For the full list of all side effects with Preotact, see the package leaflet.

Preotact must not be used in people who are hypersensitive (allergic) to parathyroid hormone or any of the other ingredients. It must also not be used in patients:

- who are having or have had radiation therapy to the skeleton,
- who have bone cancer or cancer that has spread to the bones,
- who have any disorder that affects the calcium and phosphate balance in the body,
- who have a bone disease that is not osteoporosis,
- with unexplained high levels of alkaline phosphatase (an enzyme),

- with severely reduced kidney or liver function.

Why has Preotact been approved?

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

Other information about Preotact

The European Commission granted a marketing authorisation valid throughout the European Union for Preotact on 24 April 2006.

The full EPAR for Preotact 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 Preotact, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2012.