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EPAR summary for the public

Protelos

strontium ranelate

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

What is Protelos?

Protelos is a medicine that contains the active substance strontium ranelate. It is available as 2 g sachets containing granules that are made up into an oral (by mouth) suspension.

What is Protelos used for?

Protelos is used to treat severe osteoporosis (a disease that makes bones fragile) in post-menopausal women and men who have a high risk of fracture and cannot be treated with other medicines approved for osteoporosis. In postmenopausal women, Protelos reduces the risk of vertebral and hip fractures.

The medicine can only be obtained with a prescription.

How is Protelos used?

Treatment should only be started by a doctor with experience of treating osteoporosis. As there has been some data showing an increased risk of heart attack with Protelos, the decision to prescribe Protelos should take into account the patient's individual heart risk.

Protelos is taken as one sachet once a day. The contents of the sachet are added and mixed into a glass of water to form a suspension, which is drunk just after being prepared. Protelos should be taken at least two hours after food, milk, milk products or calcium supplements, preferably at bedtime. Protelos is intended for long-term use. Patients should also receive calcium or vitamin D supplements if they are not getting enough from their diet.

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How does Protelos 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. Osteoporosis is more common in women after the menopause, when the levels of the female hormone oestrogen fall, since oestrogen helps to keep bones healthy. Osteoporosis is also observed in men due to gradual bone loss with ageing.

The active substance in Protelos, strontium ranelate, acts on the bone structure. Once in the gut, strontium ranelate releases strontium, which is absorbed into the bone. Exactly how strontium works in osteoporosis is not fully understood, but it is known to stimulate bone formation and reduce bone breakdown.

How has Protelos been studied?

Protelos has been studied in almost 7,000 elderly women in two large studies. Nearly a quarter of the patients were over 80 years of age. The first study included 1,649 women with osteoporosis who had already had a broken bone in the spine and the second included over 5,000 women whose osteoporosis was affecting the hip. In both studies, Protelos was compared with placebo (a dummy treatment) and the main measure of effectiveness was the reduction in the risk of a new bone break with Protelos. In the first study, this was based on the number of patients who, over three years, developed a new break in the spine, and in the second study, it was based on the number of patients who had a new bone break due to osteoporosis at any site other than the spine.

Protelos has also been compared with placebo in a main study involving 261 male patients at increased risk of breaking a bone. The study looked at changes in the bone density after one year of treatment.

What benefit has Protelos shown during the studies?

In the first study, Protelos reduced the risk of new breaks in the spine by 41% over three years: 21% of the 719 women who took Protelos developed a new break in the spine, compared with 33% of the 723 who took placebo.

Overall, the results of the second study taken alone were insufficient to demonstrate a benefit of Protelos in preventing bone breaks. However, when looking only at women of 74 years of age or older with particularly weak thighbones, the results suggested a reduction of the risk of breaks in the hip with Protelos.

When looking at results of the two studies taken together, fewer women in the Protelos group developed breaks at any site outside the spine (including the hip) than in the placebo group (331 out of 3,295 with Protelos compared with 389 out of 3,256 for placebo). This showed that the risk of breaking a bone is reduced.

In the study in male patients, the bone density in the lower part of the spine increased by 7% after one year of treatment in patients taking Protelos, compared with an increase of 1.7% in patients taking placebo.

What is the risk associated with Protelos?

The most common side effects with Protelos (which may affect more than 1 in 10 people) are hypersensitivity (allergic) skin reactions (rash, itching, urticaria or itchy rash, and swelling beneath the skin known as angioedema) and pain affecting muscles, bones and joints. For the full list of all side effects reported with Protelos, see the package leaflet.

Protelos must not be used in patients who have or have had venous thromboembolic events (problems due to the formation of blood clots in the veins, such as in the legs or lungs). It must not be used in people who are temporarily or permanently immobilised, such as people on bed rest or recovering from surgery.

In order to reduce the risk of heart attack, Protelos must also not be used in patients with high blood pressure that is not properly controlled or in patients with a current or past history of any of the following:

- ischaemic heart disease (such as angina or a heart attack);
- peripheral arterial disease (obstruction of the blood flow in the arteries, usually in the legs);
- cerebrovascular disease (diseases affecting the blood vessels in the brain, such as stroke).

For the full list of restrictions, see the package leaflet.

Why has Protelos been approved?

The CHMP decided that Protelos'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 Protelos?

A risk management plan has been developed to ensure that Protelos 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 Protelos, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, education materials are sent to patients and healthcare professionals prescribing Protelos reminding them of the risk of heart and circulatory problems with the medicine and of the need for regular monitoring. These materials will also remind doctors of the approved used of the medicine.

The company will also conduct a study to evaluate the effectiveness of the measures that have been put in place to reduce risk of heart and circulatory problems.

Other information about Protelos

The European Commission granted a marketing authorisation valid throughout the European Union for Protelos on 21 September 2004.

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

This summary was last updated in 04-2014.