European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

OPTRUMA

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Optruma?

Optruma is a medicine containing the active substance raloxifene hydrochloride. It is available as white, oval tablets (60 mg).

What is Optruma used for?

Optruma is used for the treatment and prevention of osteoporosis (a disease that makes bones fragile) in women who have been through the menopause. Optruma has been shown to significantly reduce vertebral fractures (breaks in the spine), but not hip fractures.
The medicine can only be obtained with a prescription.

How is Optruma used?

The recommended dose for adults and the elderly is one tablet taken once a day, with or without food. Patients may also receive calcium and vitamin D supplements if they do not get enough from their diet. Optruma is intended for long-term use.

How does Optruma 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: oestrogen slows down bone breakdown and makes the bones less likely to fracture.
The active substance in Optruma, raloxifene, is a selective oestrogen receptor modulator (SERM). Raloxifene acts as an 'agonist' of the oestrogen receptor (a substance that stimulates the receptor for oestrogen) in some tissues in the body. Raloxifene has the same effect as oestrogen in the bone, but it does not have an effect in the breast or the womb.

How has Optruma been studied?

Optruma has been studied in the treatment and in the prevention of osteoporosis in four main studies. Three studies looked at the prevention of osteoporosis in 1,764 women, who took either Optruma or placebo (a dummy treatment) for two years. The studies measured the density of the bones.
The fourth study compared the effects of Optruma with those of placebo in the treatment of osteoporosis in 7,705 women over four years. The main measure of effectiveness was how many women had vertebral (spine) fractures during the study.

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What benefit has Optruma shown during the studies?
Optruma was more effective than placebo in preventing and treating osteoporosis.
In the prevention of osteoporosis, women receiving Optruma had an increase in bone density in the hip or spine of 1.6% over two years, and those receiving placebo had a decrease of 0.8%.
When used to treat osteoporosis, Optruma was more effective than placebo in reducing the number of vertebral fractures. Over four years, in comparison with placebo, Optruma decreased the number of new vertebral fractures by 46% in women who had osteoporosis and by 32% in women who had osteoporosis and an existing fracture. There was no effect of Optruma on hip fractures.

What is the risk associated with Optruma?
The most common side effects with Optruma (seen in more than 1 patient in 10) are vasodilation (hot flushes) and flu-like symptoms. For the full list of side effects reported with Optruma, see the Package Leaflet.
Optruma should not be used in women who:
- could become pregnant;
- have or have had any blood clot disorders, including deep vein thrombosis and pulmonary embolism (a blood clot in the lungs);
- have liver disease, severe kidney disease, unexplained bleeding from the womb or endometrial cancer (cancer of the lining of the womb).

Optruma should not be used in people who may be hypersensitive (allergic) to raloxifene or any of the other ingredients.

Why has Optruma been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that Optruma had shown its effectiveness in preventing and treating osteoporosis, and had no effects on the breast or womb. The Committee decided that Optruma's benefits are greater than its risks for the treatment and prevention of osteoporosis in postmenopausal women. The Committee recommended that Optruma be given marketing authorisation.

Other information about Optruma:
The European Commission granted a marketing authorisation valid throughout the European Union for Optruma to Eli Lilly Nederland B.V. on 5 August 1998. The marketing authorisation was renewed on 5 August 2003 and on 5 August 2008.

The full EPAR for Optruma is available here.

This summary was last updated in 07-2008.