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EPAR summary for the public

Raloxifene Teva

raloxifene hydrochloride

This is a summary of the European Public Assessment Report (EPAR) for Raloxifene Teva. 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 Raloxifene Teva.

What is Raloxifene Teva?

Raloxifene Teva is a medicine that contains the active substance raloxifene hydrochloride. It is available as tablets (60 mg).

Raloxifene Teva is a 'generic medicine'. This means that Raloxifene Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Evista. For more information on generic medicines, see the question-and-answer document here.

What is Raloxifene Teva used for?

Raloxifene Teva is used for the treatment and prevention of osteoporosis (a disease that makes bones fragile) in women who have been through the menopause. Raloxifene Teva 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 Raloxifene Teva used?

The recommended dose of Raloxifene Teva is one tablet taken once a day. Patients may also receive calcium and vitamin D supplements if they do not get enough from their diet. Raloxifene Teva is intended for long-term use.

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How does Raloxifene Teva 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 Raloxifene Teva, 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 Raloxifene Teva been studied?

Because Raloxifene Teva is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Evista. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefit and risk of Raloxifene Teva?

Because Raloxifene Teva is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Raloxifene Teva been approved?

The CHMP concluded that, in accordance with EU requirements, Raloxifene Teva has been shown to have comparable quality and to be bioequivalent to Evista. Therefore, the CHMP's view was that, as for Evista, the benefit outweighs the identified risk. The Committee recommended that Raloxifene Teva be given marketing authorisation.

Other information about Raloxifene Teva

The European Commission granted a marketing authorisation valid throughout the EU for Raloxifene Teva on 29 April 2010.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 01-2015.