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EPAR summary for the public

Terrosa

teriparatide

This is a summary of the European public assessment report (EPAR) for Terrosa. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Terrosa.

For practical information about using Terrosa, patients should read the package leaflet or contact their doctor or pharmacist.

What is Terrosa and what is it used for?

Terrosa is a medicine used for the treatment of osteoporosis (a disease that makes bones fragile) in:

- women who have been through the menopause. In these patients, Terrosa has been shown to significantly reduce vertebral (spine) and non-vertebral fractures (broken bones), but not those of the hip;
- men who are at an increased risk of fractures;
- men and women who are at an increased risk of fractures due to long-term treatment with glucocorticoids (a type of steroid).

Terrosa contains the active substance teriparatide.

Terrosa is a 'biosimilar medicine'. This means that Terrosa is highly similar to a biological medicine (also known as the 'reference medicine') that is already authorised in the European Union (EU). The reference medicine for Terrosa is Forsteo. For more information on biosimilar medicines, see the question-and-answer document here.

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How is Terrosa used?

Terrosa is available as a solution for injection in cartridges (containing 600 micrograms of teriparatide) intended to be used with ServoPen Fix system. The recommended dose is 20 micrograms of Terrosa given once a day as an injection under the skin of the thigh or abdomen (belly). Patients may inject themselves once they have been trained.

Patients should receive calcium and vitamin D supplements if they do not get enough from their diet. Terrosa can be used for up to two years. The two-year course of Terrosa should be given only once during a patient's lifetime.

The medicine can only be obtained with a prescription.

How does Terrosa work?

Osteoporosis happens when not enough new bone grows to replace the bone that is naturally broken down. Gradually, the bones become less dense and more likely to break. In women, osteoporosis is more common after the menopause, when the levels of the female hormone oestrogen fall. Osteoporosis can also occur as a side effect of glucocorticoid treatment in men and women.

The active substance in Terrosa, teriparatide, is identical to part of the human parathyroid hormone. It acts like the hormone to stimulate bone formation by acting on osteoblasts (bone-forming cells). It also increases the absorption of calcium from food and prevents too much calcium being lost in the urine.

What benefits of Terrosa have been shown in studies?

Laboratory studies comparing Terrosa with Forsteo have shown that the active substance in Terrosa is highly similar to that in Forsteo in terms of structure, purity and biological activity.

Because Terrosa is a biosimilar medicine, the studies on effectiveness and safety of teriparatide carried out with Forsteo do not need to be repeated for Terrosa. A study in 54 healthy women has shown that the same doses of the two medicines given by injection under the skin produced similar levels of the active substance teriparatide in the body. Further, Terrosa and Forsteo produced similar effects on calcium levels in the blood.

What are the risks associated with Terrosa?

The most common side effect with Terrosa (seen in more than 1 patient in 10) is pain in the arms or legs. For the full list of all side effects reported with Terrosa, see the package leaflet.

Terrosa must not be used in patients who have other bone diseases such as Paget's disease, bone cancer or bone metastases (cancer that has spread to the bone), patients who have had radiation therapy of the skeleton, or patients who have hypercalcaemia (high blood calcium levels), unexplained high levels of alkaline phosphatase (an enzyme) or severe kidney disease. Terrosa must not be used during pregnancy or breastfeeding. For the full list of restrictions, see the package leaflet.

Why is Terrosa approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) considered evidence showing that Terrosa has a highly similar structure, purity and biological activity to Forsteo and is distributed in the body in the same way. This was considered sufficient to conclude that Terrosa will behave in the

same way in terms of effectiveness and safety. Thus, as for Forsteo, the benefit outweighs the identified risks and the Committee recommended that Terrosa be given marketing authorisation.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Terrosa have been included in the summary of product characteristics and the package leaflet.

Other information about Terrosa

The European Commission granted a marketing authorisation valid throughout the European Union for Terrosa on 4 January 2017.

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

This summary was last updated in 01-2017.