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Teriparatide Sun (*teriparatide*)

An overview of Teriparatide Sun and why it is authorised in the EU

What is Teriparatide Sun and what is it used for?

Teriparatide Sun is a medicine used to treat adults with osteoporosis (a disease that makes the bones fragile) in women who have been through menopause and in men who are at an increased risk of fractures. The medicine is also used to treat osteoporosis in men and women who are at an increased risk of fractures due to long-term treatment with glucocorticoids (a type of steroid).

Teriparatide Sun is a 'hybrid medicine', meaning that it is similar to a 'reference medicine' containing the same active substance, but there are certain differences between the two. The reference medicine for Teriparatide Sun is Forsteo, in which the active substance is of biological origin (produced using bacteria), whereas in Teriparatide Sun it is chemically synthesised.

Teriparatide Sun contains the active substance teriparatide.

How is Teriparatide Sun used?

Teriparatide Sun can only be obtained with a prescription. The medicine is available as a pre-filled pen and patients may inject themselves once they have been trained to do so. The recommended dose is 20 micrograms given once a day as an injection under the skin of the thigh or abdomen (tummy).

The medicine can be used for up to two years. Only one two-year course of Teriparatide Sun should be given to a patient in their lifetime.

Patients should receive calcium and vitamin D supplements if they cannot get the recommended amounts from their diet.

For more information about using Teriparatide Sun, see the package leaflet or contact your doctor or pharmacist.

How does Teriparatide Sun work?

Bones are made of a tissue that is constantly being broken down and replaced. Osteoporosis happens when the amount of new bone forming is not enough to replace the bone that is broken down. In people with osteoporosis, bones become thin and fragile and are more likely to break.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

In women, osteoporosis is more common after menopause, when levels of the hormone oestrogen fall. Osteoporosis can also occur in both sexes as a side effect of prolonged treatment with glucocorticoid medications and due to other risk factors, such as age, smoking or use of medicines that cause bone loss or high bone turnover.

The active substance in Teriparatide Sun, teriparatide, is identical to part of the human parathyroid hormone. It acts like this hormone to increase bone formation by stimulating osteoblasts (bone-forming cells), to increase the absorption of calcium from food and to help prevent too much calcium being lost in the urine.

What benefits of Teriparatide Sun have been shown in studies?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Forsteo, and do not all need to be repeated for Teriparatide Sun. As for every medicine, the company provided studies on the quality of Teriparatide Sun. Because the active substance in Forsteo is produced differently compared with Teriparatide Sun, the company also presented results from laboratory studies showing bioequivalence to the reference medicine, meaning that they both produce the same levels of active substance in the body, and are therefore expected to have the same effect.

What are the risks associated with Teriparatide Sun?

The most common side effects with Teriparatide Sun (which may affect more than 1 in 10 people) are nausea (feeling sick), pain in the arms and legs, headache and dizziness. For the full list of side effects of Teriparatide Sun, see the package leaflet.

Teriparatide Sun 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. Teriparatide Sun must also not be used during pregnancy or breastfeeding.

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

Why is Teriparatide Sun authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Teriparatide Sun was of comparable quality and was bioequivalent to the reference medicine Forsteo. Therefore, the Agency decided that the benefits of Teriparatide Sun are greater than its risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Teriparatide Sun are continuously monitored. Suspected side effects reported with Teriparatide Sun are carefully evaluated and any necessary action taken to protect patients.

Other information about Teriparatide Sun

Teriparatide Sun received a marketing authorisation valid throughout the EU on 18 November 2022.

Further information on Teriparatide Sun can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Teriparatide-Sun

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