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Sondelbay (*teriparatide*)

An overview of Sondelbay and why it is authorised in the EU

What is Sondelbay and what is it used for?

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

- women who have been through the menopause;
- men who have an increased risk of fractures;
- men and women who have an increased risk of fracture due to long-term treatment with glucocorticoids (a type of steroid).

Sondelbay is a 'biosimilar medicine'. This means that Sondelbay is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Sondelbay is Forsteo. For more information on biosimilar medicines, see here.

Sondelbay contains the active substance teriparatide.

How is Sondelbay used?

Sondelbay is available in pre-filled pens as a solution for injection under the skin. The recommended dose is 20 micrograms of Sondelbay injected once a day under the skin of the thigh or belly. Patients may inject themselves once they have been trained.

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

The medicine can only be obtained with a prescription. For more information about using Sondelbay, see the package leaflet or contact your doctor or pharmacist.

How does Sondelbay 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

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

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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 Sondelbay, 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 Sondelbay have been shown in studies?

Laboratory studies comparing Sondelbay with Forsteo have shown that the active substance in Sondelbay is highly similar to that in Forsteo in terms of structure, purity and biological activity. Studies have also shown that giving Sondelbay produces similar levels of the active substance in the body to giving Forsteo.

Because Sondelbay is a biosimilar medicine, the studies on effectiveness and safety of teriparatide carried out with Forsteo do not all need to be repeated for Sondelbay.

What are the risks associated with Sondelbay?

The safety of Sondelbay has been evaluated and, on the basis of all the studies carried out, the side effects of the medicine are considered to be comparable to those of the reference medicine Forsteo.

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

Sondelbay 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 that can be a sign of bone disease) or severe kidney disease. Sondelbay must not be used during pregnancy or breastfeeding. For the full list of restrictions, see the package leaflet.

Why is Sondelbay authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Sondelbay has a highly similar structure, purity and biological activity to Forsteo and is distributed in the body in the same way.

All these data were considered sufficient to conclude that Sondelbay will behave in the same way as Forsteo in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Forsteo, the benefits of Sondelbay outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Sondelbay

Sondelbay received a marketing authorisation valid throughout the EU on 24-03-2022.

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

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