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Kauliv (*teriparatide*)

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

What is Kauliv and what is it used for?

Kauliv is used for the treatment of osteoporosis (a disease that makes bones fragile) in the following groups:

- women who have been through the menopause;
- 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).

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

Kauliv contains the active substance teriparatide.

How is Kauliv used?

Kauliv 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. The recommended dose is 20 micrograms given once a day as an injection under the skin of the thigh or abdomen (belly).

The medicine can be used for up to two years. Only one two-year course of Kauliv should be given to a patient in their lifetime. Patients should receive calcium and vitamin D supplements if they do not get enough from their diet.

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

How does Kauliv work?

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

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In women, osteoporosis is more common after the menopause, when the levels of the female 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 low bone mass density, age or high bone turnover.

The active substance in Kauliv, 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 Kauliv have been shown in studies?

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

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

What are the risks associated with Kauliv?

The safety of Kauliv 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 effects with Kauliv (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 Kauliv, see the package leaflet.

Kauliv 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. Kauliv must also not be used during pregnancy or breastfeeding.

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

Why is Kauliv authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Kauliv 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 Kauliv 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 Kauliv 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 Kauliv?

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

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

Other information about Kauliv

Kauliv received a marketing authorisation valid throughout the EU on 12 January 2023.

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

This overview was last updated in 01-2023.