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Osenvelt (*denosumab*)

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

What is Osenvelt and what is it used for?

Osenvelt is a medicine used to prevent bone complications in adults with advanced cancer that has spread to the bone. These complications include fractures (breaks in the bone), spinal compression (pressure on the spinal cord caused by damage to the surrounding bone), or bone problems requiring radiotherapy (treatment with radiation) or surgery.

Osenvelt is also used to treat a type of bone cancer called giant cell tumour of bone in adults and in adolescents whose bones have fully developed. It is used in patients who cannot be treated by surgery or in whom surgery is likely to cause serious complications.

Osenvelt is a biological medicine and contains the active substance denosumab. It is a 'biosimilar medicine'; this means that Osenvelt is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Osenvelt is Xgeva. For more information on biosimilar medicines, see here.

How is Osenvelt used?

Osenvelt can only be obtained with a prescription. It is available as a solution that is given as an injection under the skin in the thigh, belly or upper arm.

To prevent bone complications in patients with cancer that has spread to the bone, Osenvelt is given once every 4 weeks. In patients with giant cell tumour of bone, the medicine is given once every 4 weeks, with an additional dose 1 week and 2 weeks after the first dose.

Patients should take calcium and vitamin D supplements while being treated with Osenvelt.

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

How does Osenvelt work?

The active substance in Osenvelt, denosumab, is a monoclonal antibody which has been designed to recognise and attach to a protein called RANKL. This protein activates osteoclasts, the cells in the body that are involved in breaking down bone tissue. By attaching to and blocking RANKL, denosumab

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reduces the formation and activity of osteoclasts. This reduces the loss of bone, making fractures and other serious bone complications less likely. RANKL is also involved in activating the osteoclast-like cells in giant cell tumour of bone. Treatment with denosumab therefore prevents these cells from growing and breaking down bone, allowing normal bone to replace the tumour.

What benefits of Osenvelt have been shown in studies?

Laboratory studies comparing Osenvelt with the reference medicine, Xgeva, have shown that the active substance in Osenvelt, denosumab, is highly similar to the denosumab in Xgeva in terms of structure, purity and biological activity. A study has also shown that giving Osenvelt produces similar levels of denosumab in the body to those seen with Xgeva.

In addition, a study compared the effectiveness of the denosumab in Osenvelt with that of another medicine containing denosumab in 479 women with osteoporosis (a disease that makes bones fragile) who have been through the menopause. After a year of treatment, bone mineral density in the spine (a measure of how strong the bones are) increased by around 5% in both women who received Osenvelt and those who received Prolia.

Because denosumab works in a similar way in osteoporosis and in the conditions Osenvelt is intended to treat, a specific study on the effectiveness of Osenvelt in these conditions is not needed.

What are the risks associated with Osenvelt?

The safety of denosumab in Osenvelt 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, Xgeva.

For the complete list of side effects and restrictions with Osenvelt, see the package leaflet.

The most common side effects with Osenvelt (which may affect more than 1 in 10 people) include hypocalcaemia (low levels of calcium in the blood) and musculoskeletal pain (pain in the muscles and bones). Other common side effects (which may affect up to 1 in 10 people) include osteonecrosis in the jaw (damage to the bones of the jaw, which could lead to pain, sores in the mouth and loose teeth).

Hypocalcaemia mostly occurs within the first 2 weeks of starting treatment and can be severe; however, it can be managed with calcium and vitamin D supplementation.

Osenvelt must not be used in patients with wounds from dental or mouth surgery that have not yet healed, or in people with severe, untreated hypocalcaemia.

Why is Osenvelt authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Osenvelt has a highly similar structure, purity and biological activity to Xgeva and is distributed in the body in the same way. In addition, a study has shown that Osenvelt and Xgeva are equally safe and effective in Osenvelt's intended uses.

These data were considered sufficient to conclude that Osenvelt will have the same effects as Xgeva in its authorised uses. Therefore, the Agency's view was that, as for Xgeva, the benefits of Osenvelt 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 Osenvelt?

The company that markets Osenvelt will provide a card to inform patients about the risk of osteonecrosis of the jaw and to instruct them to contact their doctor if they have symptoms.

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

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

Other information about Osenvelt

Osenvelt received a marketing authorisation valid throughout the EU on 14 February 2025.

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

This overview was last updated in 03-2025.