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Wyost (*denosumab*)

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

What is Wyost and what is it used for?

Wyost 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.

Wyost 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.

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

How is Wyost used?

Wyost can only be obtained with a prescription. It is available as a solution for injection.

To prevent bone complications in patients with cancer that has spread to the bone, Wyost is given once every 4 weeks as an injection under the skin in the thigh, belly or upper arm.

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 Wyost.

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

How does Wyost work?

The active substance in Wyost, 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 reduces the formation and activity of osteoclasts. This reduces the loss of bone, making fractures and

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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 Wyost have been shown in studies?

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

In addition, a study compared the effectiveness of the denosumab in Wyost with that of Prolia (another medicine containing denosumab) in 463 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 Wyost and those who received Prolia.

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

What are the risks associated with Wyost?

The safety of denosumab in Wyost 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 Wyost, see the package leaflet.

The most common side effects with Wyost (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.

Wyost 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 Wyost authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Wyost 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 the denosumab in Wyost is as effective as another denosumab-containing medicine, Prolia, in women with osteoporosis. Denosumab works in a similar way in the treatment of osteoporosis and in Wyost's intended uses.

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

The company that markets Wyost 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 Wyost have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Wyost

Wyost received a marketing authorisation valid throughout the EU on 17 May 2024.

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

This overview was last updated in 05-2024.