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Jubbonti (*denosumab*)

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

What is Jubbonti and what is it used for?

Jubbonti is a medicine used to treat the following conditions:

- osteoporosis (a disease that makes bones fragile) in women who have been through the menopause and in men who have an increased risk of fracture (broken bones). In women who have been through the menopause, Jubbonti reduces the risk of fractures in the spine and elsewhere in the body, including in the hip;
- bone loss in men receiving treatment for prostate cancer that increases their risk of fracture. Jubbonti reduces the risk of fractures in the spine;
- bone loss in adults at increased risk of fractures who are treated long term with corticosteroid medicines given by mouth or injection.

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

How is Jubbonti used?

Jubbonti can only be obtained with a prescription. It is available in prefilled syringes. The medicine is given once every 6 months as an injection under the skin in the thigh, belly or back of the arm. During treatment with Jubbonti, the doctor should ensure that the patient is taking calcium and vitamin D supplements. Jubbonti can be given by someone who has been trained to give the injections.

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

How does Jubbonti work?

The active substance in Jubbonti, denosumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a protein in the body called RANKL. RANKL is involved in activating osteoclasts, the cells in the body that are involved in breaking down bone tissue. By

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attaching to and blocking RANKL, denosumab reduces the formation and activity of the osteoclasts. This reduces the loss of bone and maintains bone strength, making fractures less likely to happen.

What benefits of Jubbonti have been shown in studies?

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

In addition, a study involving 463 women with osteoporosis who have been through the menopause showed that Jubbonti is as effective as Prolia at increasing bone mineral density (a measure of how strong the bones are) in the spine. After a year of treatment, bone mineral density increased by around 5% in both women who received Jubbonti and those who received Prolia.

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

What are the risks associated with Jubbonti?

The safety of Jubbonti 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, Prolia.

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

The most common side effects with Jubbonti (which may affect more than 1 in 10 people) include pain in the arms or legs, and bone and muscle pain. Cellulitis (inflammation of deep skin tissue) can occur in up to 1 in 100 people. Hypocalcaemia (low blood calcium), hypersensitivity (allergy), osteonecrosis of the jaw (damage to the bones of the jaw, which could lead to pain, sores in the mouth or loosening of teeth) and unusual fractures of the thigh were seen in up to 1 in 1000 people.

Jubbonti must not be used in people with hypocalcaemia.

Why is Jubbonti authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Jubbonti has a highly similar structure, purity and biological activity to Prolia and is distributed in the body in the same way. In addition, a study has shown that Jubbonti and Prolia are equivalent in terms of safety and effectiveness in women with osteoporosis who have been through the menopause.

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

The company that markets Jubbonti 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 experience symptoms.

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

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

Other information about Jubbonti

Jubbonti received a marketing authorisation valid throughout the EU on 16 May 2024.

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

This overview was last updated in 05-2024.