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Stoboclo (*denosumab*)

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

What is Stoboclo and what is it used for?

Stoboclo 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 fractures (broken bones). In women who have been through the menopause, Stoboclo reduces the risk of fractures in the spine and elsewhere in the body, including the hips;
- bone loss in men receiving treatment for prostate cancer that increases their risk of fractures. Stoboclo reduces the risk of fractures in the spine;
- bone loss in adults at increased risk of fractures due to long term treatment with corticosteroid medicines given by mouth or injection.

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

How is Stoboclo used?

The medicine can only be obtained with a prescription. Stoboclo is available as a solution for injection in prefilled syringes.

Stoboclo is given once every 6 months as an injection under the skin in the thigh, abdomen (belly) or back of the arm. During treatment with Stoboclo, the doctor should ensure that the patient is receiving calcium and vitamin D supplements. Stoboclo can be given by someone who has been trained in how to give injections appropriately.

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

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How does Stoboclo work?

The active substance in Stoboclo, denosumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a specific 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 attaching to and blocking RANKL, denosumab reduces the formation and activity of osteoclasts. This reduces bone loss and maintains bone strength, making fractures less likely to happen.

What benefits of Stoboclo have been shown in studies?

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

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

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

What are the risks associated with Stoboclo?

The safety of Stoboclo 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 of Stoboclo, see the package leaflet.

The most common side effects with the denosumab in Stoboclo (which may affect more than 1 in 10 people) include musculoskeletal pain (pain in the muscles and bones) and pain in the arms and legs. Other side effects (which may affect up to 1 in 100 people) include cellulitis (inflammation of the deep skin tissue). Hypocalcaemia (low blood calcium levels), hypersensitivity (allergic reactions), osteonecrosis in the jaw (damage to the bones of the jaw, which could lead to pain, sores in the mouth and loose teeth), and fractures in the bones of the upper legs may affect up to 1 in 1,000 people taking denosumab.

Stoboclo must not be used in people with hypocalcaemia.

Why is Stoboclo authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Stoboclo has a highly similar structure, purity and biological activity to Prolia and is distributed in the body in the same way. In addition, studies in postmenopausal osteoporosis have shown that Stoboclo and Prolia are equivalent in terms of safety and effectiveness in this condition.

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

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

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

Other information about Stoboclo

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

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

This overview was last updated in 03-2025.