Wrightington, Wigan and Leigh Teaching Hospitals
NHS Foundation Trust

Denosumab biosimilar (Stoboclo©) - Ageing and Complex Medicine

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Patient Information

Ageing and Complex Medicine

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What is Denosumab?

Denosumab is a medicine used to treat bone loss in postmenopausal women with osteoporosis or in men at high risk of broken bones. Denosumab can also be used to treat bone loss that results from surgery, or treatment with medicines for prostate cancer or long-term glucocorticoids. It belongs to a group of medicines called monoclonal antibodies and is given by an injection under the skin (subcutaneous).

How does Denosumab work?

Denosumab is a protein (monoclonal antibody) that works by blocking a specific protein called RANKL. This protein usually helps certain cells (called osteoclasts) break down bone. By stopping RANKL, denosumab prevents these cells from forming and working, which means less bone is broken down. Treatment with denosumab makes bone stronger and less likely to break.

How is Denosumab made?

Denosumab is a biological medicine. Biological medicines are medicines made or derived from living cells. Biological medicines were first used to treat people with serious illnesses in the UK over 20 years ago and they have improved the lives of millions of people worldwide.

What versions of Denosumab are available in the UK?

Until recently, only one pharmaceutical company (Amgen) made denosumab. Now other companies can make biosimilar denosumab and these will become available for use when the patent protecting the Amgen product (Prolia) expires.

What is Biosimilar Denosumab?

Biosimilar denosumab is a highly similar copy of the original denosumab medicine. The World Health Organisation (WHO) defines a biosimilar as a medicine that is similar in terms of quality, safety and effectiveness to the original licensed medicine.

Are Biosimilars safe?

The Medicines and Healthcare Products Regulatory Agency (MHRA) is the organisation in the UK who regulate medicines. All medicines, including biosimilars, must pass rigorous tests for quality, biological activity, safety and effectiveness.

What does treatment with Biosimilar Denosumab mean for you?

Whether you are due to start treatment with denosumab for the first time or if your treatment is changing from Prolia to biosimilar denosumab (Stoboclo©), you can expect the same results. Biosimilar denosumab devices and packaging may look different to Prolia. If you are trained to inject yourself, ensure you are familiar with the new device and know how to use it and what dose to inject.

The National Institute for Health and Care Excellence (NICE) produces guidance for healthcare. If NICE recommends the original biological medicine in their guidance, the same recommendation applies to the biosimilar medicines. All versions of denosumab can cause similar side effects. If you experience any problems with your treatment, report it promptly to your treating clinician, nurse or pharmacist.

What are the benefits of Biosimilars?

Biological medicines are often expensive and the number of conditions the NHS can treat with them is increasing. Biosimilar medicines are highly similar to the original medicines and have the same quality, safety and effectiveness as well as usually being less expensive. Therefore, the savings made by using biosimilars allow the NHS to treat more patients and invest in new medicines to further improve patient care.

Further advice

If you have further questions about denosumab or biosimilars, then please speak to a member of your clinical or pharmacy team.

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Denosumab biosimilar PIL



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