

Denosumab

Prolia® 60mg solution for injection in a pre-filled syringe

Other formats

If you need this information in another format such as audio tape or computer disk, Braille, large print, high contrast, British Sign Language or translated into another language, please telephone the PALS desk on 01271 314090.

Please read this leaflet carefully before taking this medicine and keep it as a reminder. If you have any further questions, please contact the Rheumatology Nurse Advice Line on 01271322359 or your GP.

What is Denosumab and what is it used for?

Denosumab contains a protein (monoclonal antibody) that blocks the action of the cells that break down bones. It prevents bone loss, improves bone density and therefore decreases risk of fractures. Treatment with Denosumab makes bone stronger and less likely to break.

Denosumab is used:

- to treat osteoporosis in women after the menopause (postmenopausal), reducing the risk of spinal, non-spinal and hip fractures.
- to treat bone loss in men that results from a reduction in hormone (testosterone) level caused by surgery or treatment with medicines for prostate cancer.
- for men at increased risk of fractures.

Denosumab is not recommended for anyone under 18 years of age. The use of Denosumab in children and adolescents has not been studied.

Special precautions

Please tell your GP / health care professional if:

- you have an allergy to latex (the needle cover on the pre-filled syringe contains a derivative of latex).
- you have or have ever had severe kidney problems, kidney failure or have needed dialysis.
- you suffer from long-term or recurring ear infections

Dental care

It is important to maintain good oral hygiene when being on treatment with Denosumab. A dental examination should be considered before you start treatment with Denosumab. Please inform your GP / healthcare professional if:

- you have or ever had cancer and had or are receiving chemotherapy or radiotherapy
- you are taking steroids
- you do not receive routine dental care or have gum disease
- you are a current smoker

If you are receiving dental treatment, or dental surgery is planned, please tell your dentist that you are being treated with Denosumab and inform your GP / healthcare professional about the dental work due.

Using other medicines

Please tell your GP, healthcare professional or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breastfeeding

Denosumab is not recommended if you are pregnant. Therefore, it is important to tell your GP / healthcare professional if you are pregnant, think you may be pregnant or plan to get pregnant.

It is not known whether Denosumab is excreted in breast milk. It is important to discuss with your doctor if you are breastfeeding or planning to do so.

Driving and using machines

Denosumab has no or negligible influence on the ability to drive or use machines.

If you have an intolerance to some sugars

If you have been told by your GP / healthcare professional that you have an intolerance to sugars (sorbitol E420), contact them before taking Denosumab.

How to use Denosumab

You should also take calcium and vitamin D supplements whilst being treated with Denosumab. Your GP / healthcare professional will discuss this with you.

The usual dose of Denosumab is one pre-filled syringe of 60mg administered once **every 6 months**, as a single injection under the skin (subcutaneous). The best places to inject are the top of your thighs or the abdomen. The outer area of your upper arm can also be used. Mark the next injection date on your personal calendar to keep a record of the next injection date.

You will receive the first dose as an outpatient in hospital. Your GP, practice nurse or community nurse will administer the subsequent doses. You will need a blood test taking prior to your next Denosumab injection. You will need to organise this with your GP surgery and then book a date with them for your injection.

If you stop using Denosumab

To get the most benefit from your treatment, it is important to use Denosumab 6 monthly and for as long as your GP prescribes it for you. Please talk to your GP / healthcare professional before you consider stopping the treatment.

Possible side effects

Like all medicines, Denosumab can cause side effects, although not everybody gets them.

Common side effects include:

- Urinary tract infections and upper respiratory tract infections
- Pain, tingling or numbness that moves down your leg (sciatica)
- Constipation
- Rash
- Arm or leg pain (pain in extremity)

Less common side effects include:

- Skin infections, abdominal pain and discomfort associated with diverticulitis,
- Ear infection,
- Skin condition with itching, redness and/or dryness (eczema).

Rare side effects:

- Persistent pain and/or non-healing sores of the mouth or jaw (osteonecrosis of the jaw)
- Atypical (unusual) thigh bone fracture

Very rare side effects:

- Low calcium levels in blood (hypocalcaemia)

If you experience any of these side effects, please seek help from your GP / healthcare professional.

If any of the side effects get serious or if you notice any side effects or unusual symptoms not listed on this leaflet, please contact your GP, pharmacist or nurse.

Further information

If you have any further questions, contact the Rheumatology Nurse Advice Line on 01271 322359.

PALS

The Patient Advice and Liaison Service (PALS) ensures that the NHS listens to patients, relatives, carers and friends, answers questions and resolves concerns as quickly as possible. If you have a query or concern call 01271 314090 or e-mail ndht.pals@nhs.net. You can also visit the PALS and Information Centre in person at North Devon District Hospital, Barnstaple.

Have your say

Northern Devon Healthcare NHS Trust aims to provide high quality services. However, please tell us when something could be improved. If you have a comment or compliment about a service or treatment, please raise your comments with a member of the staff or the PALS team in the first instance.

'Care Opinion' comments forms are on all wards or online at www.careopinion.org.uk.

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