

Information for patients

Information for patients Denosumab (Prolia)



What is osteoporosis?

Osteoporosis literally means 'porous bones'. Our bones are made up of a thick outer shell and a strong inner mesh, this looks like a honeycomb made up of tiny struts of bone. In osteoporosis, some of these struts become thin or break, making bones more fragile and prone to fracture. Osteoporosis often remains undetected until a bone is broken. Broken bones (fractures) in osteoporosis often occur in the wrist, hip or spinal bones (vertebrae) but osteoporosis affects all of the bones in the body. Fractures in osteoporosis can occur very easily, for example in a simple fall or through lifting awkwardly.

Who is at risk?

Hormones including oestrogen in women and testosterone in men help keep bones healthy. After the menopause, oestrogen levels drop and as more bone is removed than replaced this leads to bone loss and fragility.

Similarly, surgery or medication that stops the production of oestrogen or testosterone may be used to treat patients with breast or prostate cancer. This can also lead to bone loss and osteoporosis

What is Prolia and how does it work?

Prolia contains denosumab, a protein (monoclonal antibody) that interferes with the action of another protein, in order to treat bone loss and osteoporosis.

Bone is a living tissue and is renewed all the time by a process called bone turnover. Bone turnover describes the removal and replacement of bone by specialist bone cells. It helps to repair damage from everyday activities. Treatment with Prolia slows down the process of bone turnover. Prolia stops the cells that break down bone (osteoclasts), allowing the cells that rebuild bone (osteoblasts) to work more effectively and bring the process back into balance. Prolia is not used to relieve the pain of osteoporotic fractures but to improve bone strength and reduce the risk of fractures.

How is it given?

Prolia is given as a subcutaneous (just under the skin) injection.

How often do I need to have this treatment?

Prolia is given every six months. It is important that each injection is as close to six months after the last injection as possible. Each pack of Prolia contains a reminder card with stickers that can be removed from the box. Use the peel-off stickers to mark the next injection date on your calendar and/or the reminder card to keep a record of the next injection date.

Who should use Prolia?

Prolia is used to treat:

- Osteoporosis in women after the menopause (postmenopausal) reducing the risk of spinal, non-spinal and hip fractures.
- Bone loss that results from a reduction in hormone (testosterone) level caused by surgery or treatment with medicines in patients with prostate cancer.

Who should not use Prolia?

Before treatment, your doctor will check whether you have low calcium levels in the blood. This will need to be treated before you receive Prolia.

You should not use Prolia if:

- You are allergic (hypersensitive) to denosumab or any of the other ingredients of Prolia.
- You have an intolerance to sorbitol E420 (a kind of sugar)
- You have an allergy to latex. The needle cover on the pre-filled syringe contains a derivative of latex. Please discuss with your doctor before using this treatment.
- You are breast feeding, pregnant; think you may be pregnant; or plan to get pregnant. Prolia has not been tested and is not recommended in pregnant women.

What should I do whilst on treatment?

It is important to maintain good oral hygiene. You may be advised to have a dental examination before you start treatment. If you are having dental treatment please tell your dentist that you are being treated with Prolia.

Do I need to take any extra supplements?

Most people having treatment with Prolia should also take calcium and vitamin D supplements. Your doctor will advise you about this.

What happens if I miss a treatment?

If a dose of Prolia is missed, the injection should be given as soon as possible. Injections should be scheduled 6 months from the date of the last injection.

What happens if I stop treatment?

To get the most benefit from your treatment, it is important to use Prolia for as long as your doctor prescribes it for you. Please talk to your doctor before you consider stopping the treatment.

What are the side effects?

As with all medications patients may rarely develop side effects, these include:

- Skin infections (cellulitis). Swollen, red area of skin, most commonly in the lower leg, that feels hot and tender. There may also be fever (raised temperature).
- Osteonecrosis of the jaw
This is a very rare condition in which some of the cells in the affected bone die. It can lead to delayed healing and problems usually following major dental work. - There have been only a very small number of cases described worldwide in patients treated with osteoporosis, so the risk associated is extremely low. However, it is important to have regular dental care and to let your dentist know if you are receiving treatment with Prolia.

Prolia may occasionally cause other side effects. If you experience any symptoms that you think may be due to your treatment please talk to your doctor or contact the Metabolic Bone Centre.

How can I find out more?

There are many things you can do to help your bones. Further information about osteoporosis and its treatment can be obtained from the staff in the Metabolic Bone Centre.

Please contact:

The Metabolic Bone Centre
The Northern General Hospital
Herries Road
Sheffield
S5 7AU

Telephone: 0114 271 5340

Nurses' helpline: 0114 226 6547

Alternatively, you can request information from the National Osteoporosis Society.

National Osteoporosis Society
Camerton, Bath, BA2 0PJ
Website: www.nos.org.uk
Email: info@nos.org.uk

Telephone: 0845 450 0230 (9am-5pm Mon-Fri)
For National Osteoporosis Society publications and information sheets, please go to www.nos.org.uk or telephone 01761 471771.

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