

5.4 Denosumab (Prolia)

Patient Information Leaflet

Introduction

Denosumab (Prolia) is a treatment for post-menopausal osteoporosis.

What is osteoporosis?

Osteoporosis is a condition that causes gradual weakening of the bones, making them more likely to fracture. The condition mainly affects the elderly and is most common in women after their menopause.

Bone is a living tissue maintained by cells that make new bone and cells that remove old bone. Normally there is a balance of old bone being removed and new bone being formed. As we age, however, loss of old bone may be more than the formation of new bone, causing the bones to thin. This leads to osteoporosis.

Osteoporosis may cause no symptoms at first but it can cause bones to break more easily, especially after a fall. It may also cause loss of height, persistent back pain and a stooping posture.

What is denosumab?

Denosumab, which has the brand name Prolia is a medicine used to treat osteoporosis. It works by reducing the activity of cells that break down bone. This slows down loss of bone material and can help maintain bone strength.

Although you may not see or feel any difference after taking the medicine, denosumab will help to reduce your risk of fractures.

How is denosumab taken?

The usual dose of denosumab is 60mg which is contained in a pre-filled syringe. This is given once every six months as a single injection under the skin, either in the upper thighs or abdomen (stomach).

The first injection is given by a trained practitioner at your GP surgery, local hospital or clinic. After that, you will continue to be given the injections at your GP practice in most cases.

In order to get the most benefit from the treatment, it is important that you attend your appointments to receive an injection every six months.

It is vital that you have a blood test two weeks before each injection, and sometimes two weeks after an injection, to check your calcium levels.

It is your responsibility to have these blood tests. Please contact your GP surgery to book this.

It is also very important to take good care of your teeth and gums, and visit the dentist for regular check-ups every six months whilst on the treatment. This is to monitor for a rare condition called osteonecrosis of the jaw. Please make sure your dentist knows that you are receiving denosumab treatment.

How can I remind myself of my next denosumab injection?

You should always check with the doctor or nurse giving you the injection when and where you will be receiving your next injection.

There is a reminder card with stickers contained in each pack of denosumab. It is a good idea to mark the next injection date on your personal calendar with the peel-off stickers. The reminder card can

also be used to record your next injection date so if you want, you can ask the doctor/nurse if you can keep this card.

What if I forget to have my denosumab injection?

If you miss your denosumab injection, you should arrange for it to be given as soon as possible.

The injections after this should be scheduled every six months from the last injection date.

Do I need to take additional supplements?

It is best to take vitamin D supplements (with or without calcium) while you are receiving Prolia injections. Your consultant or GP will discuss this with you in more detail. You should take these supplements exactly as directed.

How long will denosumab take to work?

Research has shown an increase in bone density as early as three months after starting denosumab injections.

When can I stop my denosumab injections?

As denosumab works to reduce bone loss in the long term, it is important that you keep receiving it for as long as it is prescribed for you.

If the medicine is causing you any problems, or you are considering stopping denosumab for any other reasons, you should discuss this with your consultant or GP first.

Will I have side effects from denosumab?

Like all medicines, denosumab can cause side effects. However, not everyone will be affected by these. Some of the side effects may only be a mild inconvenience.

You must tell your consultant or GP if you experience any problems that you think may be related to denosumab, particularly if they are serious or persistent.

It is also important to let your GP know if you notice side effects that are not listed in this leaflet.

Common side effects (affects one to 10 users in 100):

- Chest infections
- Urinary tract infections – these can cause frequent and/or painful urination, and sometimes blood in the urine
- Sciatica (pain, tingling or numbness which spreads out down the leg)
- Abdominal discomfort
- Eczema (itching, redness and dryness of skin)
- Constipation
- Skin rash

Uncommon side effects (affects one to 10 users in 1,000):

- Skin infections (skin may become red, hot, tender)
- Ear infection

Rare side effects (affects one user in 10,000)

- Low levels of calcium in the blood
- Painful sores of the mouth or jaw
- Osteonecrosis of the jaw which means the death of bone tissue. It can cause pain, swelling, or gum infections, loosening of teeth and poor healing of the gums especially after dental work
- Allergic reactions, such as swelling of the face or a skin rash (hives)
- Unusual thigh bone fractures

If you experience pins and needles, muscle cramps or spasms, seizures or confusion, this could indicate low levels of calcium in your blood – please contact your GP immediately.

If you notice any teeth loosening, mouth pain or mouth sores that will not heal, please tell your dentist immediately.

Can I take my other medications?

You should let your consultant know the names of all the medicines you are taking as denosumab may interact with some medications. This includes medicines you may have bought over the counter without prescriptions.

The common medicines that may interact with denosumab include:

- Steroids
- Hormone replacement therapy (HRT) or other drugs that contain oestrogen
- Some anti-hormone medicines used in cancer treatment

You should inform your consultant if you are taking any of the medications listed above.

Sometimes your consultant may suggest that you take medicines that are known to interact with each other, particularly if the benefits of taking these medicines together would outweigh the risks. If this is the case, your consultant may want to monitor you more closely or change the dose of either medicine.

Can I drink alcohol?

Alcohol is safe within reason as it has no known interactions with denosumab. However, it is advised that you stay within the government guidelines for alcohol consumption, currently no more than 14 units per week for both men and women.

Can I drive and operate machinery as normal?

Denosumab should not affect your ability to drive and operate machines. However, if you are not feeling well enough to drive or use machines due to side effects of denosumab, you should wait until you feel better, or discuss this with your consultant.

Can I have immunisation injections whilst receiving Prolia?

There is no evidence that immunisations of any type should be avoided.

Other treatments

Before taking combinations of prescribed and over-the-counter medications, you are advised to discuss this with your GP.

Can I find out more?

You can find out more from the following:

Royal Osteoporosis Society

Tel: 0808 800 0035 (9am to 4.30pm, Monday to Thursday; 9am to 4pm, Friday)

Website: www.theros.org.uk

If you have any questions, or if there is anything you do not understand about this leaflet, please contact: