

PATIENT INFORMATION ON DENOSUMAB

Brand name: Prolia

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- **how you should take your medicine**
- **the possible side effects**
- **other precautions you should take while taking denosumab.**

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking denosumab you should see your doctor regularly to make sure the treatment is working and to minimise any possible side effects.
- If you are worried about any side effects you should contact your specialist as soon as possible.
- Denosumab should *not* be taken with some other osteoporosis medicines such as bisphosphonates like alendronate (Fosamax, Alendro) or risedronate (Actonel), or other treatments such as raloxifene (Evista), strontium (Protos) or teriparatide (Forteo). These should be stopped before you start denosumab.
- Do not stop using denosumab until advised by your doctor

For more information about OSTEOPOROSIS see the Osteoporosis Australia website www.osteoporosis.org.au/ or phone Osteoporosis Australia on 1800 242 141.

What is denosumab?

Denosumab (brand name Prolia) is a medicine used to treat osteoporosis. Osteoporosis is a common disease, which causes bones to become fragile and brittle so that they break (fracture) more easily even as a result of normal activity (as distinct from a fall).

Fractures are painful and restrict a person's ability to carry out their normal daily tasks. Denosumab reduces the risk of a broken bone or fracture.

How does it work?

Bone is constantly changing, with old bone breaking down and new bone being formed to take its place. This usually happens in a balanced way. If the cycle becomes unbalanced, bone breaks down faster than it is replaced. This leads to osteoporosis.

Denosumab is a medicine that slows or stops the bone breaking down. As a result, bone strength increases and the risk of fracture is reduced.

What benefit can you expect from your treatment?

Since osteoporosis is usually not painful (until a fracture occurs) you will not 'feel' any immediate benefit from your treatment with denosumab.

The treatment controls osteoporosis but does not cure it. It is therefore important to continue to use denosumab even if you feel well. Do not stop using teriparatide until advised by your doctor.

You may be asked to have tests to check the effect of treatment on your bones. For example, a bone mineral density test is usually done after one to two years of treatment. This is a type of x-

ray, which involves a very small amount of radiation.

Tests of urine or blood are also sometimes used to measure the effects of treatment on bone formation and breakdown.

How is denosumab used?

Denosumab is given as an injection under the skin (subcutaneously).

It is very important that you follow the instructions for using denosumab carefully, including the instructions for storage and disposal (see page 3). Ask your doctor or pharmacist to explain anything you do not understand.

How is the injection given?

Denosumab may be injected into the top of the thigh, the abdomen or the back of the arm. It comes in a single-use pre-filled syringe to make the injection easier.

You or your carer should have proper training before using the injection. If you are not sure ask your doctor, nurse or pharmacist before attempting the injection.

For safety, each pre-filled syringe has an automatic needle guard that is activated to cover the needle after complete delivery of the syringe contents.

The needle guard contains a latex derivative. If you have latex allergy or sensitivity, tell your doctor.

Do not use denosumab if the solution is cloudy or discoloured. There may be some translucent to white particles of protein in the solution; however the medicine can still be used.

What is the dosage and when should it be given?

The denosumab dose is 60 milligrams. This is given every 6 months.

Do not use more or less denosumab, or use it more often than prescribed by your doctor.

Can other medicines be taken with denosumab?

It is safe to take most other medicines when you are taking denosumab. However, it should *not* be taken with some other osteoporosis medicines (see *Precautions* on page 3).

Your doctor will usually recommend that you take calcium and vitamin D as additional treatment for osteoporosis. Do not stop taking these medicines unless advised by your doctor.

How long is the treatment continued?

Treatment with denosumab is usually given every 6 months. Your doctor will review your progress each year. Once you have had one fracture your chance of having another one is high, so it is important to keep taking the medicine as long as it is effective and as long as no serious side effects occur.

Are there any side effects?

Most people who take denosumab do not experience side effects. Tell your doctor if you are concerned about possible side effects.

Most common possible side effects

Most common side effects include:

- *fever and chills*
- *itchy (pruritis), hot, tender, red or dry skin such as dermatitis or eczema.* This may not be restricted to the injection site and often gets better without on its own.

Less common or rare possible side effects

Less common or rare side effects include:

- *infection of skin, joint or heart valve*
- *skin ulcers or pancreatitis*
- *low calcium blood levels*
- *muscle and joint pain*
- *stomach and back pain, nausea, vomiting and/or sweating*
- Rarely denosumab may cause an *allergic reaction* with a widespread rash or a feeling of tightness in the chest and difficulty breathing.
- A potentially serious but very rare side effect with denosumab is *osteonecrosis of the jaw (ONJ)*. This presents with jaw pain. It usually occurs after dental work which does not heal properly. There are a few reports in osteoporosis patients. For most patients receiving denosumab injections, the benefits outweigh the potential risk of ONJ because fractures can be associated with significant complications and even death. As a precaution, it is recommended that dental infections should be treated, and planned

extractions performed before starting denosumab treatment.

There are a number of other uncommon side effects and precautions that are described in the leaflet that comes with the medicine. Read this information and call your doctor if you have any problems while using this medicine. Denosumab is a new medicine so its long-term side effects are not yet known.

What precautions are necessary?

Blood tests

- Monitoring blood tests are not usually required for people taking denosumab although in certain situations these may be needed.
- Denosumab should not be used if you have hypocalcaemia (low blood calcium level). Calcium levels will be checked and corrected before you start treatment. You will also need to take additional calcium and vitamin D if you are likely to develop hypocalcaemia. If you have poor kidney function you are more likely to develop hypocalcaemia, so blood tests to monitor your calcium levels will be required.

Other medical conditions

- Denosumab can be given if you have severe kidney disease; however close monitoring of calcium levels is needed (see above).

Use with other medicines

- You should tell your doctor (including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines. You should also mention your treatment when seeing other health professionals.
- Denosumab should *not* be taken with some other osteoporosis medicines such as bisphosphonates like alendronate (Fosamax, Alendro), risedronate (Actonel) and zoledronate (Aclasta) or other treatments such as raloxifene (Evista), strontium (Protos) or teriparatide (Forteo).
- The risk of side effects from the low doses of aspirin used to prevent heart attack and strokes is not increased when taken with denosumab.

How to store and dispose of denosumab

- Keep the medicine in the pre-filled syringe out of reach of children.
- Store it in the refrigerator but do not freeze it.
- Protect it from light.
- Dispose of the syringe in a puncture-resistant container (sharps box). Talk to your doctor or pharmacist about how to dispose of the sharps box.

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

If you are taking denosumab you should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.

The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicines mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medicine. It can be reproduced in its entirety but cannot be altered without permission from the ARA.

The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.