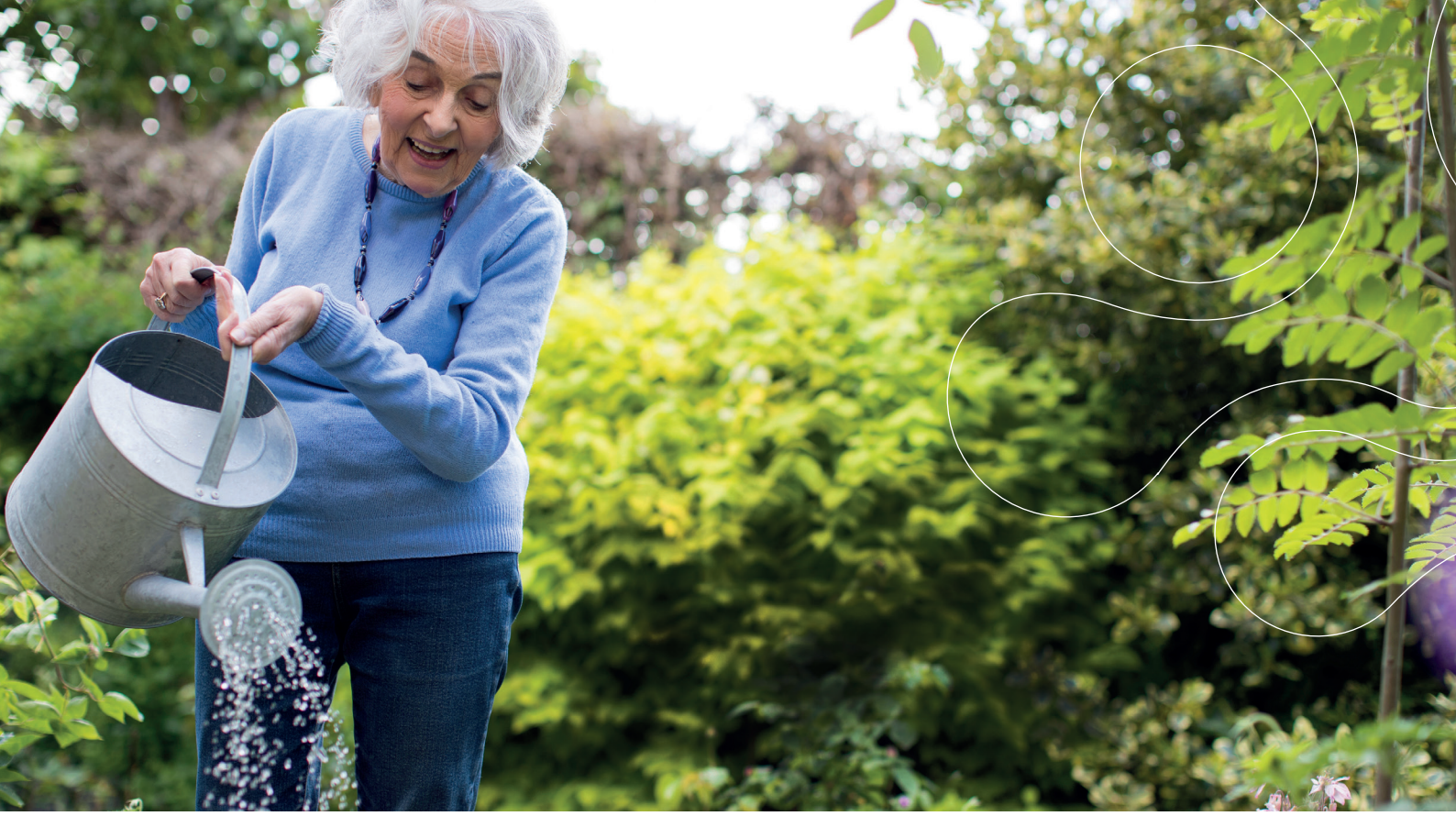


AMGEN care
www.amgencare.ie

PROLIA® (DENOSUMAB)
A GUIDE TO UNDERSTANDING PROLIA®

This booklet is only intended for patients who have been prescribed Prolia®

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160.

Please report any potential quality issue with the Amgen product you have received, by calling us on +44 (0) 1223 436441 or Freephone 1800 535 160 and providing us with the details. Please ensure that you keep your packaging, so we are able to identify your product more easily.

WELCOME TO PROLIA® (DENOSUMAB)

Your doctor, nurse, or healthcare provider has given you this booklet because you have recently been diagnosed with osteoporosis and are being treated with a medication called Prolia®. It is also possible that you have recently suffered an osteoporosis-related fracture (broken bone) or you have an inability to tolerate being treated with another osteoporosis medication and have been switched to Prolia®.

In this booklet, we will share with you some information about important aspects of osteoporosis treatment, how Prolia® works, and possible side effects that may cause you to seek advice from your doctor on continuing your treatment.

Our most important piece of advice to you: continue your doctor's prescribed treatment.

Please read both this patient booklet and the Patient Information Leaflet (PIL) that comes with your Prolia® pack, also available at www.medicines.ie/medicines/prolia-33455/patient-info.

Your doctor will give you a Patient Reminder Card, which contains important safety information you need to be aware of before and during your treatment with Prolia®. You can also see the Patient Reminder Card at www.medicines.ie/medicines/prolia-33455/educational-material-patient.

- Visit the patient website www.amgencare.ie to see more information about Prolia® and osteoporosis.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

Remember, you should always ask your doctor or nurse any specific questions about your condition or treatment.

WHAT IS OSTEOPOROSIS?

Osteoporosis is a silent, chronic disease. And even though you can't see it or feel it happening, if it is left untreated, your bones may weaken and become more porous (less bone density) and prone to breaks. This means that seemingly simple activities could result in a broken bone. Many men and women with osteoporosis have no symptoms, but they are at a higher risk of breaking bones, particularly those in the spine, hip and wrists.[1,2]

Why are my bones weaker?

Your bones are a living tissue and continuously being renewed. Your skeleton forms the framework for your body. It enables you to move and helps protect internal organs. Everyone has cells that remove bone in their body (osteoclasts) and the other cells that rebuild bone (osteoblasts).[3] This ongoing process is part of what keep your bones strong. In osteoporotic patients, this balance is disrupted because the bone is lost faster than it can be rebuilt. 1 in 2 women and 1 in 4 men over 50 will experience an osteoporotic fracture in their lifetime.[2]

NORMAL BONE

Higher bone density

OSTEOPOROTIC

Lower bone density

Osteoporosis in women: During menopause, oestrogen, a hormone that helps protect bone in women, sharply decreases. This results in bone loss, and it's the reason why so many women are at risk for developing osteoporosis at this time. In post-menopausal osteoporosis, the bone removing cells (osteoclasts) cause you to lose bones at a rate that is too fast.[4] In the 5 to 7 years after menopause women can lose up to 20% of their bone mass leaving them with bones that are more fragile and more likely to break.[5]

Osteoporosis in men: Men also experience bone loss, which can lead to osteoporosis, but this tends to occur later in life.[6]

HOW DOES PROLIA® WORK?

Prolia® is used to treat osteoporosis in:[7]

- **Women:** after the menopause (postmenopausal) who are at high risk of fracture (broken bones) or cannot use another osteoporosis medicine, or if other osteoporosis medicines did not work well.
- **Men:** who have an increased risk of fracture. It also treats bone loss that results from a reduction in hormone (testosterone) level caused by surgery or treatment with medicines in patients with prostate cancer.
- **Men & women:** where bone loss has resulted from long-term treatment with glucocorticoids (class of steroid hormones), leaving patients at increased risk of fracture.

Prolia® is a prescription medicine proven to help strengthen your bones. Prolia® works by reducing bone removing cell (osteoclasts) activity. This in turn results in increased bone density which will strengthen the bone and make it less likely to break. Prolia® is given as an injection just under the skin once every six months. You should take calcium and vitamin D as your doctor tells you while you receive Prolia®.[7,8]

The treatment effect of Prolia® does wear off if treatment is stopped, so it is very important you continue to get your injection every six months unless your doctor tells you to stop the treatment. If you do stop therapy with Prolia®, your doctor will suggest an alternative treatment for osteoporosis with another medication.[9,10]

WHY AM I BEING PRESCRIBED PROLIA®?

As we get older, our risk of bone breaks and fractures increases. **Osteoporosis causes your bones to become weaker and more fragile and falls can become more common.** Lifestyle changes and keeping active can help to prevent falling. Your doctor and nurse will also have spoken to you about taking calcium and vitamin D to supplement your diet, which are important in overall bone health.[9] Drug treatments, such as Prolia®, can strengthen bone and reduce the risk of breaking bones.

Prolia® in women[7]: Prolia® is used to improve bone strength and hence reduce the risk of fractures in women with osteoporosis after the menopause. You may not see any changes or feel any different in yourself when you are taking it, but it is important to continue taking Prolia® as it can help reduce the risk of fractures.

Prolia® in men[7]: treatment with Prolia® can also be prescribed for men with osteoporosis who are at high risk of fracture and in prostate cancer patients who have suffered bone loss caused by effect of surgery/treatments.

Also, treatment with Prolia® can be beneficial in patients with bone loss associated with long-term steroid therapy who have an increased risk of fracture.[7]

Your doctor will have considered your medical history and circumstances, as well as information available before deciding to prescribe Prolia®. This might have included clinical trials demonstrating:[7]

- The ability of Prolia® to reduce bone loss and gradually restore bone mass
- The ability of Prolia® to reduce the risk of fracture
- The side effect profile of Prolia®

- Tell your doctor if you have or have ever had severe kidney problems, kidney failure or have needed dialysis or are taking medicines called glucocorticoids (such as prednisolone or dexamethasone), which may increase your risk of getting low blood calcium if you do not take calcium supplements.

POSSIBLE SIDE EFFECTS[11]

Like all medicines, Prolia® can cause side effects. Everyone's reaction to a medicine is different.
It is difficult to predict which side effects you may experience from taking a particular medicine and you may not get any side effects at all. Your doctor or nurse will discuss the side effects with you.
It is important to tell your healthcare provider if you are having any problems with your medicine.

Possible side effects associated with Prolia® include:

Very Common side effects (may affect more than 1 in 10 people):	
• Bone, joint, and/or muscle pain which is sometimes severe	• Arm or leg pain (pain in extremity)

Common side effects (may affect up to 1 in 10 people):	
• Painful urination, frequent urination, blood in the urine, inability to hold your urine	• Abdominal discomfort
• Upper respiratory tract infection	• Rash
• Pain, tingling or numbness that moves down your leg (sciatica)	• Skin condition with itching, redness and/or dryness (eczema)
• Constipation	• Hair loss (alopecia)

For further information and a full list of side effects associated with Prolia®, please refer to the patient information leaflet that comes with your Prolia® pack, also available at www.medicines.ie/medicines/prolia-33455/patient-info.

Reporting of side effects:
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160.

- Uncommonly, patients receiving Prolia® may develop skin infections (predominantly cellulitis). **Please tell your doctor immediately if you develop any of these symptoms while being on treatment with Prolia®:** swollen, red area of skin, most commonly in the lower leg, that feels hot and tender, and possibly with symptoms of fever.
- Rarely, patients receiving Prolia® may develop pain in the mouth and/or jaw, swelling or non-healing of sores in the mouth or jaw, discharge, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs of bone damage in the jaw (osteonecrosis). **Tell your doctor and dentist immediately if you experience such symptoms while being treated with Prolia® or after stopping treatment.**
- Rarely, patients receiving Prolia® may have low calcium levels in the blood (hypocalcaemia). Symptoms include spasms, twitches or cramps in your muscles, and/or numbness or tingling in your fingers, toes or around your mouth and/or seizures, confusion, or loss of consciousness. **If any of these apply to you, tell your doctor immediately.** Low calcium in the blood may also lead to a change in heart rhythm called QT prolongation which is seen by electrocardiogram (ECG).
- Rarely unusual fractures of the thigh bone may occur in patients receiving Prolia®. **Contact your doctor if you experience new or unusual pain** in your hip, groin or thigh as this may be an early indication of a possible fracture of the thigh bone.
- Rarely, allergic reactions may occur in patients receiving Prolia®. Symptoms include swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin, wheezing or difficulty breathing. **Please tell your doctor if you develop any of these symptoms while being treated with Prolia®.**

FREQUENTLY ASKED QUESTIONS:

HOW IS PROLIA® ADMINISTERED?

Prolia® is a single subcutaneous (under-the-skin) injection given every six months.[11]

WHERE IN THE BODY IS THE INJECTION GIVEN?

The Prolia® injection is given in the thigh, abdomen or upper arm.[11]

WHERE WILL I GET MY INJECTIONS?

Your doctor or nurse will decide what it is best: for you or a carer to inject Prolia®, or for this to be done by a healthcare provider. Please discuss this with your prescribing doctor to identify a convenient Prolia® administration plan. If your doctor has instructed you to give yourself the injection, please see in the next pages a step-by-step guide on how to do it and visit www.amgencare.ie to see a video demonstration.

HOW TO REMEMBER THE NEXT INJECTION?

The manufacturers of Prolia® (Amgen®) have a patient support programme - please ask your doctor or nurse how to enroll. Also, mark the next injection date on your calendar, phone, reminder card, and/or Prolia® Passport card to keep a record of the next injection date. You can download the Prolia® Passport card on www.amgencare.ie.

HOW OFTEN IS PROLIA® GIVEN?

You only need a Prolia® injection once every six months.[11] Prolia® has been developed as a long-term treatment, so is recommended that you consult your doctor on the date for a potential next injection.

IF YOU FORGOT TO TAKE PROLIA®

If a dose of Prolia® is missed, the injection should be administered as soon as possible. Thereafter, injections should be scheduled every 6 months from the date of the last injection.[11]

STOPPING PROLIA®

To get the most benefit from your treatment in reducing the risk of fractures, it is important to use Prolia® for as long as your doctor prescribes it for you. Do not stop your treatment without contacting your doctor.[11]

TREATMENT MONITORING

Your doctor or nurse will assess how you are managing your condition while on treatment at regular intervals, and may order repeat DEXA scans (which measure bone density)[4] to see how your bone treatment is working. Osteoporosis is a chronic condition that requires a long term treatment to prevent bone loss and fractures.

WHAT SHOULD I DO IF I MISSED MY INJECTION?

Simply administer it (if you were trained to do it) or book in for an injection as soon as it is convenient for you and your healthcare provider.[11] The treatment effect of Prolia® does wear off if treatment is stopped, so it is important you continue to get your injection every six months. If you miss an injection you might increase your risk of a fracture.[9,10]

HOW TO USE THE PROLIA® PRE-FILLED SYRINGE WITH AUTOMATIC NEEDLE GUARD (ANG)[11]

Unless you have been instructed by your doctor or healthcare provider do not try to give yourself the injection. You can also find step by step instructions on how to use the ANG pre-filled syringe in the Patient Information Leaflet.

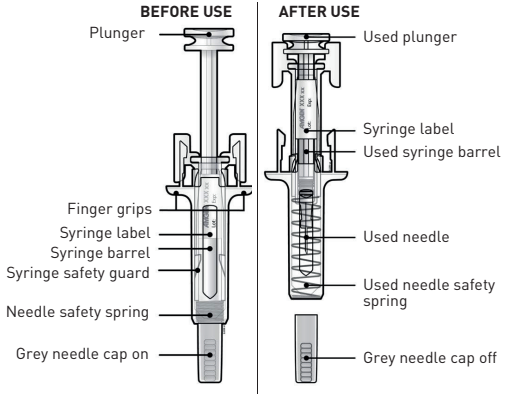
The ANG pre-filled syringe is used like a standard syringe. After delivering the full injection, a needle guard is automatically activated as you release pressure from the plunger, safely covering the injection needle. The ANG pre-filled syringe is disposed of as you would a standard syringe.

A step by step video demonstration showing how to administer your Prolia® ANG pre-filled syringe is available at: www.amgencare.ie

Important: Before you use a Prolia® pre-filled syringe with automatic needle guard, read this important information:

- **It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.**
- Prolia® is given as an injection into the tissue just under the skin (subcutaneous injection).

Guide to parts



X **Do not** remove the grey needle cap from the pre-filled syringe until you are ready to inject.

X **Do not** use the pre-filled syringe if it has been dropped on a hard surface. Use a new pre-filled syringe and call your doctor or healthcare provider.

X **Do not** attempt to activate the pre-filled syringe prior to injection.

X **Do not** attempt to remove the clear pre-filled syringe safety guard from the pre-filled syringe.

Call your doctor or healthcare provider if you have any questions.

STEP 1: Prepare

A Remove the pre-filled syringe tray from the package and gather the supplies needed for your injection: alcohol wipes, a cotton ball or gauze pad, a plaster and a sharps disposal container.

For a more comfortable injection, leave the pre-filled syringe at room temperature for about 30 minutes before injecting. Wash your hands thoroughly with soap and water.

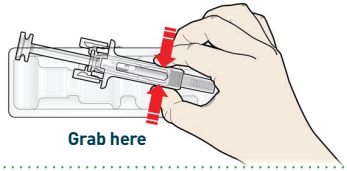
On a clean, well-lit work surface, place the new pre-filled syringe and the other supplies.

X **Do not** try to warm the syringe by using a heat source such as hot water or microwave.

X **Do not** leave the pre-filled syringe exposed to direct sunlight.

X **Do not** shake the pre-filled syringe.

- **Keep the pre-filled syringe out of the sight and reach of children.**



B Open the tray, peeling away the cover. Grab the pre-filled syringe safety guard to remove the pre-filled syringe from the tray.

For safety reasons:

X **Do not** grasp the plunger.

X **Do not** grasp the grey needle cap.

C Inspect the medicine and pre-filled syringe.

X **Do not** use the pre-filled syringe if:

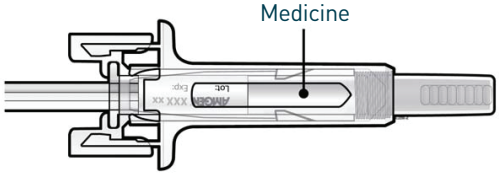
X The medicine is cloudy or there are particles in it. It must be a clear, colourless to slightly yellow solution.

X Any part appears cracked or broken.

X The grey needle cap is missing or not securely attached.

X The expiry date printed on the label has passed the last day of the month shown.

In all cases, call your doctor or healthcare provider.



STEP 2: Get ready

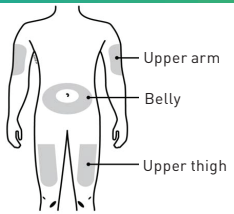
A Wash your hands thoroughly. Prepare and clean your injection site.

You can use:

- Upper part of your thigh.
- Belly, except for a 5 cm (2-inch) area right around your belly button.
- Outer area of upper arm (only if someone else is giving you the injection).

Clean the injection site with an alcohol wipe. Let your skin dry.

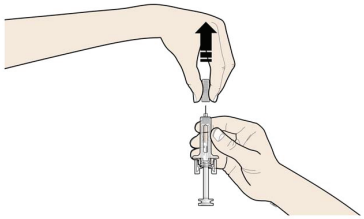
X **Do not** touch the injection site before injecting.



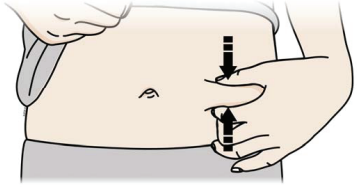
! X **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.

STEP 2: Get ready (continued)

B Carefully pull the grey needle cap straight out and away from your body.



C Pinch your injection site to create a firm surface.



! It is important to keep the skin pinched when injecting.

STEP 3: Inject

A Hold the pinch.
INSERT the needle into skin.
X **Do not** touch the cleaned area of the skin.

B PUSH the plunger with slow and constant pressure until you feel or hear a "snap". Push all the way down through the snap.

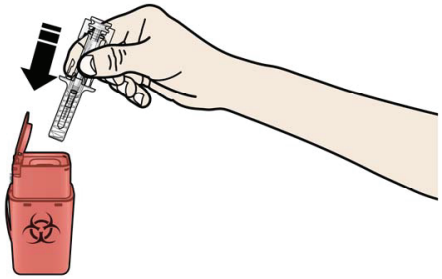
! It is important to push down through the "snap" to deliver your full dose.

C RELEASE your thumb. Then LIFT the syringe off skin.

After releasing the plunger, the pre-filled syringe safety guard will safely cover the injection needle.
X **Do not** put the grey needle cap back on used pre-filled syringes.

STEP 4: Finish

A Discard the used pre-filled syringe and other supplies in a sharps disposal container.



Medicines should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines no longer required.
These measures will help to protect the environment.
Keep the syringe and sharps disposal container out of sight and reach of children.
X **Do not** reuse the pre-filled syringe.
X **Do not** recycle pre-filled syringes or throw them into household waste.

B Examine the injection site.
If there is blood, press a cotton ball or gauze pad on your injection site.
Do not rub the injection site.
Apply a plaster if needed.

If, after reading this brochure, you have any further questions, or you would like to stop taking your Prolia® treatment, please contact your doctor or nurse. **If any side effects do occur, please contact your doctor immediately.**

References:
1. International Osteoporosis Foundation. What is osteoporosis? [Available at: www.iofbonehealth.org/what-osteoporosis-0. Accessed: August 2020] **2.** Irish Osteoporosis Society. About Osteoporosis. [Available at: www.irishosteoporosis.ie/about-osteoporosis/. Accessed: August 2020] **3.** International Osteoporosis Foundation. Introduction to bone biology [Available at: www.iofbonehealth.org/introduction-bone-biology-all-about-our-bones. Accessed: August 2020] **4.** Drake M, et al. Clin Ther 2015 Vol37 pp1837-1850 **5.** National Osteoporosis Foundation. What Women Need to Know. [Available at: www.nof.org/preventing-fractures/general-facts/what-women-need-to-know/. Accessed: August 2020] **6.** International Osteoporosis Foundation. Osteoporosis in men [Available at: www.iofbonehealth.org/osteoporosis-men. Accessed: August 2020] **7.** Prolia® (denosumab) Summary of Product Characteristics. [Available at: www.medicines.ie/medicines/prolia-33455/smpc] **8.** Baron R, et al. Bone. 2011;48:677–92. **9.** Kanis, JA et al. Osteoporos Int. 2019;30(1):3–44; **10.** Tsourdi E, et al. Bone. 2017;105:11–7. **11.** Prolia® (denosumab) Patient Information Leaflet. [Available at: www.medicines.ie/medicines/prolia-33455/patient-info]

PLEASE REFER TO THE PATIENT INFORMATION LEAFLET THAT CAME WITH YOUR MEDICINE OR AVAILABLE AT www.medicines.ie/medicines/prolia-33455/patient-info

Visit the patient website www.amgencare.ie for more information (for quick access, scan the below QR code with your phone's camera or QR reader app)

AMGEN®

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