Automatic Needle Guard (ANG)
Pre-filled Syringe Training Guide

Introduction
This ANG pre-filled syringe is used like a conventional syringe. Administer the medication by pushing the plunger all the way down. 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 conventional syringe.

Before you start
- Ensure that you have read the package leaflet instructions provided with this product before use.
- For a more comfortable injection, leave the pre-filled syringe at room temperature for about 30 minutes before injecting.
- Based upon the package leaflet instructions, select and prepare an appropriate injection site.

ADMINISTER INJECTION & DEPLOY NEEDLE GUARD

Remove grey needle cover.

A Pinch the injection site to create a firm surface.

It is important to keep skin pinched when injecting.

Hold the pinch. INSERT needle into skin.

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

It's important to push down through the “snap” to deliver the full dose.

C RELEASE your thumb. Then LIFT syringe off skin.

After releasing the plunger, the pre-filled syringe safety guard will safely cover the injection needle.

Discard used pre-filled syringe and other supplies in a sharps disposal container.
PROLIA® (denosumab)  
Brief Prescribing Information

Please refer to the Summary of Product Characteristics (SmPC) before prescribing Prolia. Pharmaceutical Form: Pre-filled syringe with automatic needle guard containing 60 mg of denosumab in 1 ml solution for injection for single use only. Contains sorbitol (E420). Indication: Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures. Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures. Dosage and Administration: 60 mg Prolia administered as a subcutaneous injection once every 6 months. Patients must be supplemented with calcium and vitamin D. No dosage adjustment required in patients with renal impairment. Not recommended in paediatric patients under 18 years of age. Give Prolia patients, the package leaflet and patient reminder card. Contraindications: Hypocalcaemia or hypersensitivity to the active substance or to any of the product excipients. Special Warnings and Precautions: Hypocalcaemia: Identify patients at risk for hypocalcaemia. Hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiation of therapy. Clinical monitoring of calcium levels is recommended before each dose and, in patients predisposed to hypocalcaemia, within 2 weeks after the initial dose. Measure calcium levels if suspected symptoms of hypocalcaemia occur. Renal Impairment: Patients with severe renal impairment (creatinine clearance < 30 ml/min) or receiving dialysis are at greater risk of developing hypocalcaemia. Regular monitoring of calcium levels in these patients is especially important. Skin Infections: Patients receiving Prolia may develop skin infections (predominantly cellulitis) requiring hospitalisation and if symptoms develop then they should contact a healthcare professional immediately. Osteonecrosis of the jaw (ONJ): ONJ has been reported rarely with Prolia 60 mg every 6 months. Delay treatment in patients with unhealed open soft tissue lesions in the mouth. A dental examination with preventative dentistry and an individual benefit-risk assessment is recommended prior to treatment with Prolia in patients with concomitant risk factors. Refer to the SmPC for risk factors for ONJ. Patients should be encouraged to maintain good oral hygiene, receive routine dental check-ups and immediately report oral symptoms during treatment with Prolia. While on treatment, invasive dental procedures should be performed only after careful consideration and avoided in close proximity to Prolia administration. The management plan of patients who develop ONJ should be set up in close collaboration between the treating physician and a dentist or oral surgeon with expertise in ONJ. Atypical femoral fracture (AFF): AFF has been reported in patients receiving Prolia. Discontinuation of Prolia therapy in patients suspected to have AFF should be considered pending evaluation of the patient based on an individual benefit-risk assessment. Concomitant medication: Patients with rare hereditary problems of fructose intolerance should not use Prolia. Dry natural rubber: The needle cover of the pre-filled syringe contains dry natural rubber (a derivative of latex) which may cause allergic reactions. Interactions: Prolia did not affect the pharmacokinetics of midazolam, which is metabolized by cytochrome P450 3A4 (CYP3A4). There are no clinical data on the co-administration of denosumab and hormone replacement therapy (HRT), however the potential for pharmacodynamic interactions would be considered low. Pharmacokinetics and pharmacodynamics of Prolia were not altered by previous alendronate therapy. Fertility, pregnancy and lactation: There are no adequate data on the use of Prolia in pregnant women and it is not recommended for use in these patients. It is unknown whether denosumab is excreted in human milk. A risk/benefit decision should be made in patients who are breast feeding. Animal studies have indicated that the absence of RANKL during pregnancy may interfere with maturation of the mammary gland leading to impaired lactation post-partum. No data are available on the effect of Prolia on human fertility. Undesirable Effects: The following adverse reactions have been reported: Very common (≥ 1/10) pain in extremity, musculoskeletal pain. Common (≥ 1/100 to < 1/10) urinary tract infection, upper respiratory tract infection, sciatica, cataracts, constipation, abdominal discomfort, rash, and eczema. Uncommon (≥ 1/1000 to < 1/100): Diverticulitis, cellulitis, and ear infection. Rare (≥ 1/10,000 to < 1/1000): Osteonecrosis of the jaw, hypocalcaemia (including severe symptomatic hypocalcaemia) and atypical femoral fractures. In the postmarketing setting, musculoskeletal pain (including severe cases) rare cases of severe symptomatic hypocalcaemia, and rare events of hypersensitivity (including rash, urticaria, facial swelling, erythema and anaphylactic reactions) have been reported. Please consult the Summary of Product Characteristics for a full description of undesirable effects. Pharmaceutical Precautions: Prolia must not be mixed with other medicinal products. Store at 2°C to 8°C (in a refrigerator). Prolia may be exposed to room temperature (up to 25°C) for a maximum single period of up to 30 days in its original container. Once removed from the refrigerator Prolia must be used within this 30 day period. Do not freeze. Keep in outer carton to protect from light. Legal Category: POM. Presentation, Basic Costs and Marketing Authorisation Number: Prolia 60 mg: Pack of 1 pre-filled syringe with automatic needle guard: £183.00, EU/1/10/618/003. Marketing Authorisation Holder: Amgen Europe B.V., Minervum 7061, NL-4817 ZK Breda, The Netherlands. Further information is available from Amgen Limited, 240 Cambridge Science Park, Milton Road, Cambridge, CB4 0WD. Prolia is a registered trademark of Amgen Inc. Date of PI preparation: June 2015 (Ref: UKIE-P-162-0515-106861)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard Adverse events should also be reported to Amgen Limited on +44 (0) 1223 436712

Reference:
1. Prolia® (denosumab) Summary of Product Characteristics and patient leaflet