Prolia® (denosumab) for the treatment of women with postmenopausal osteoporosis

Information for GPs

What is Prolia®?

Prolia® is a human monoclonal antibody licensed for the treatment of osteoporosis in postmenopausal women, and in men, at increased risk of fracture, and for the reduction of risk of spine and hip fracture.1 Prolia® given subcutaneously twice yearly for 36 months is associated with a reduction in the risk of vertebral, nonvertebral, and hip fractures in women with osteoporosis compared with placebo.2 Prolia® is suitable for administration in a primary care setting,1,3 enabling patients to receive treatment closer to home. Please refer to the Summary of Product Characteristics for further details.

National Institute for Health and Care Excellence (NICE) recommendation—October 2010 (TA 204)3

Prolia® is recommended as a treatment option for the secondary prevention of osteoporotic fragility fractures only in postmenopausal women at increased risk of fractures who are unable to comply with the special instructions for administering alendronate and either risedronate or etidronate, or have an intolerance of, or a contraindication to, those treatments. Prolia® is recommended as a treatment option for the primary prevention of osteoporotic fragility fractures only in postmenopausal women at increased risk of fractures:

• Who are unable to comply with the special instructions for administering alendronate and either risedronate or etidronate, or have an intolerance of, or a contraindication to, those treatments; and

• Who also meet specific criteria regarding T-score, age and number of independent clinical risk factors for fracture

Prolia® administration

The recommended dose of Prolia® is 60 mg administered as a single subcutaneous injection once every 6 months into the thigh, abdomen or upper arm.1 Patients must be adequately supplemented with calcium and vitamin D.1 No dose adjustment is required in patients with renal impairment, or the elderly (aged ≥65 years).1 Administration should be performed by an individual who has been adequately trained in injection techniques.1

Calcium monitoring

Clinical monitoring of calcium levels is recommended before each dose and, in patients predisposed to hypocalcaemia, within 2 weeks after the initial dose.1 Calcium levels should be checked if suspected symptoms of hypocalcaemia occur.1 Patients with severe renal impairment (creatinine clearance <30 ml/min) or receiving dialysis are at greater risk of developing hypocalcaemia.1 Regular monitoring of calcium levels in these patients is especially important.1 Please refer to the Summary of Product Characteristics for further details.

Osteonecrosis of the jaw (ONJ)

ONJ has been reported rarely with Prolia® 60 mg every 6 months.1 A dental examination is recommended prior to treatment with Prolia® in patients with concomitant risk factors.1 Good oral hygiene practices and routine dental check-ups should be maintained during treatment with Prolia®.1 While on treatment, patients should avoid invasive dental procedures if possible.1 Please refer to the Summary of Product Characteristics for further details.

Storage and ordering

Prolia® should be stored in a refrigerator (2°C to 8°C). Do not freeze. Prolia® has a shelf life of 36 months. Keep the pre-filled syringe in the outer carton to protect from light.1 Prolia® may be stored at room temperature (up to 25°C) for up to 30 days in the original container. Once removed from the refrigerator it must be used within this 30-day period.1 Prolia® can be delivered directly to your practice within 24 hours. To order, contact Movianto UK – Product code 9002794

Telephone: 01234 248500 (8.30am to 4.30pm; Monday to Friday)
Fax: 01234 248705
Email: orders.uk@movianto.com
Alternatively, Prolia® can be provided to patients through retail pharmacy by writing an FP10.
Prolia® (denosumab) Brief Prescribing Information

Please refer to the Summary of Product Characteristics (SmPC) before prescribing Prolia. Pharmacological 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 is required in patients with renal impairment. Not recommended in paediatric patients under 18 years of age. 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. For information on known risk factors for ONJ, please refer to the SmPC. A dental examination is recommended prior to treatment with Prolia in patients with concomitant risk factors. Good oral hygiene practices and routine dental check-ups should be maintained during treatment with Prolia. While on treatment, patients should avoid invasive dental procedures if possible. 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. Dry Natural Rubber: The needle cover of the pre-filled syringe contains dry natural rubber (a derivative of latex) which may cause allergic reactions. Concomitant Medications: Patients with rare hereditary problems of fructose intolerance should not use Prolia. 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 undesirable effects 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 < 1/1,000): 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 anaaphylactic 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: E193.00; 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: August 2014 (Ref: DMB-GBR-AMG-514-2014-P).

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.