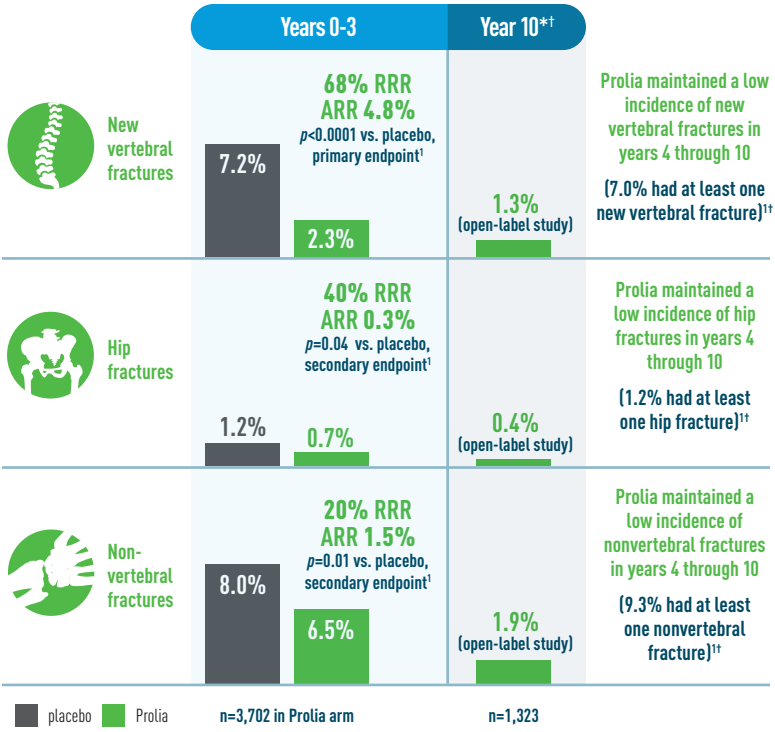
Prolia® is indicated:[1]

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- As a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- As a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- As a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- As a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Pr prolia® denosumab

Fracture incidence with Prolia treatment over 10 years in postmenopausal osteoporosis[1]



ARR=absolute risk reduction; RRR=relative risk reduction

* Annualized yearly subject incidence.

† In women who received Prolia in the 3-year placebo-controlled phase and continued on therapy in the open-label FREEDOM extension.

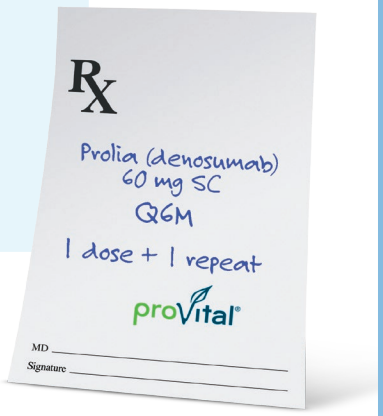
A randomized, double-blind, placebo-controlled study in postmenopausal patients with osteoporosis receiving 60 mg Prolia (n=3,902) or placebo (n=3,906) subcutaneously once every 6 months for 3 years. In the long-term, open-label extension study, women received Prolia for up to 10 years. Subjects were between the ages of 60 and 91 years and had bone mineral density T-scores <-2.5 and ≥-4.0. All women received at least 1000 mg calcium and at least 400 IU vitamin D supplementation per day.[1]

Adapted from Prolia Product Monograph.[1]

Prolia is taken twice a year by subcutaneous injection[1]

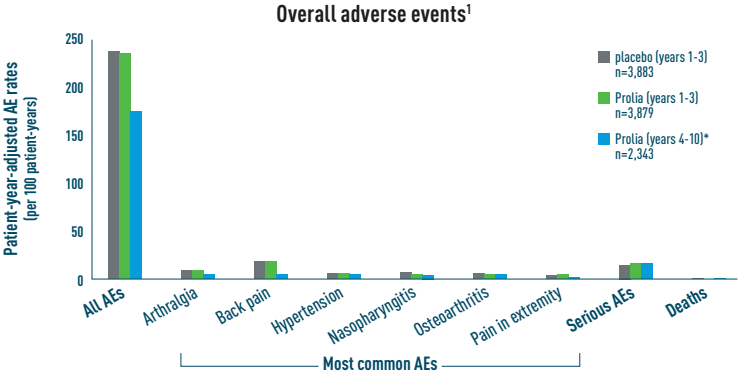
Administration of Prolia is to only be performed by an adequately trained injector.

1 60 mg SC injection every **6** months



Please see the Product Monograph for complete dosing and administration information.

Prolia was generally well tolerated up to 10 years in patients with postmenopausal osteoporosis



Adverse events with Prolia in the extension study (years 4 through 10, n=2,343) were similar to those observed at 3 years (n=3,879)[1]

* Based on data from 7 years of the extension study for patients who received Prolia in the 3-year placebo-controlled phase and continued on therapy (years 4 through 10 of Prolia treatment; n=2,343).

Adapted from Prolia Product Monograph.[1]

Multiple vertebral fractures following discontinuation of Prolia treatment

Multiple vertebral fractures may occur following discontinuation of treatment with Prolia, particularly in patients with a history of vertebral fracture[1]

Advise patients not to interrupt Prolia therapy without their physician's advice[1]

Evaluate the individual benefit/risk before discontinuing treatment with Prolia[1]

If Prolia treatment is discontinued, consider transitioning to an alternative anti-resorptive therapy.[1]

Clinical use:

Prolia is not indicated for use in pediatric patients.

Contraindications:

- Hypersensitivity to the drug or any component of the product. Anaphylactic reactions have been reported.
- Hypocalcemia
- Patients who are pregnant or trying to become pregnant. Verify the pregnancy status of women of reproductive potential prior to initiating Prolia. Advise them of the risk of Prolia use in pregnancy and to use effective contraception during therapy; and for at least 5 months after the last dose.

Relevant warnings and precautions:

- Contains same active ingredient as XGEVA®; do not use concurrently
- Adequate intake of calcium and vitamin D is important in all patients
- Hypocalcemia; clinical monitoring of calcium levels is recommended
- In severe renal impairment or dialysis, there is a greater risk of hypocalcemia; adequate intake of calcium and vitamin D is important
- Serious infections
- Epidermal and dermal adverse events
- Osteonecrosis of the jaw (ONJ); risk may increase with duration of exposure to Prolia; evaluate for ONJ risk factors before starting treatment; dental examination is recommended for those with risk factors; good oral hygiene practices should be maintained during treatment and invasive dental procedures should be avoided
- Atypical femoral fractures
- Multiple vertebral fractures following discontinuation of Prolia treatment
- Significant suppression of bone remodelling
- Potential for greater sensitivity in older patients
- Not recommended in nursing women
- Potential for female partner and fetal exposure unlikely when taken by men
- Latex sensitivity

For more information:

Please consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to adverse reactions, drug interactions and dosing information which have not been discussed in this piece.

The Product Monograph is also available by calling Amgen at 1-866-502-6436.

References: 1. Prolia Product Monograph. Amgen Canada Inc., June 25, 2019. **2.** Data on File. Amgen Canada Inc.

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Prolia experience across all 6 indications:

Postmenopausal women with osteoporosis; to increase bone mass in: men with osteoporosis, men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, women and men due to sustained systemic glucocorticoid therapy, women and men who are starting or have recently started long-term glucocorticoid therapy.[1,2]

>400,000
patients in Canada

>11.7 MILLION
patient-years worldwide

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