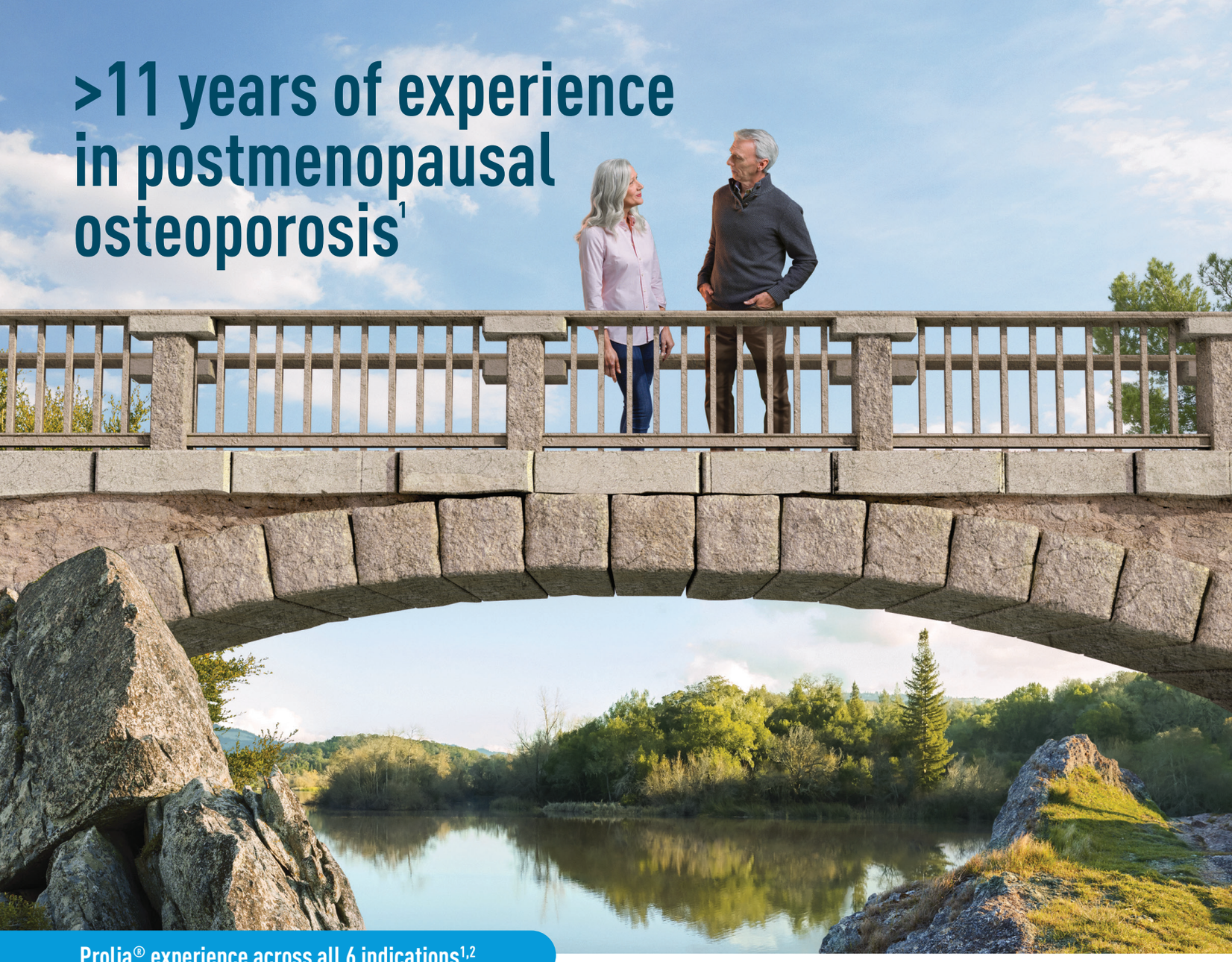
>11 years of experience in postmenopausal osteoporosis[1]



Prolia® experience across all 6 indications[1,2]

>500,000
patients in Canada

>11.7 MILLION
patient-years worldwide

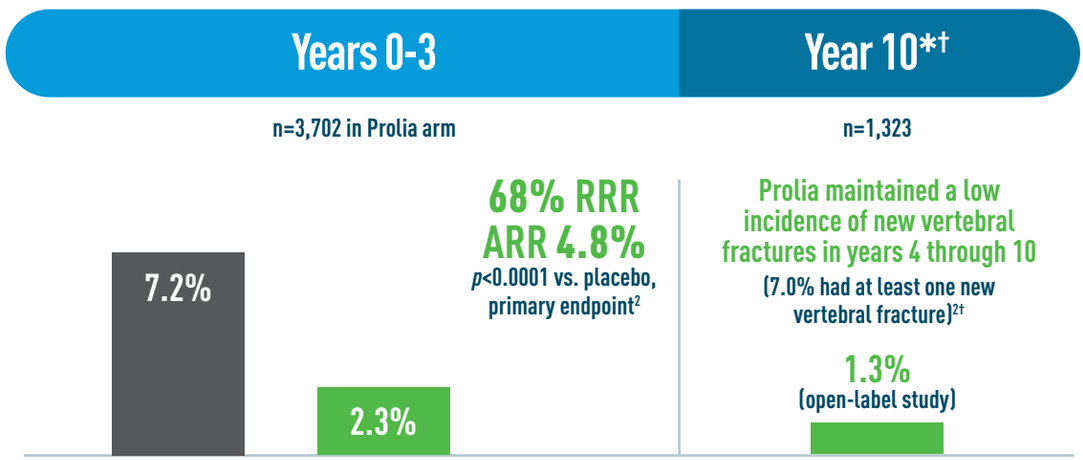
Prolia (denosumab injection) is indicated:[2]

- 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.

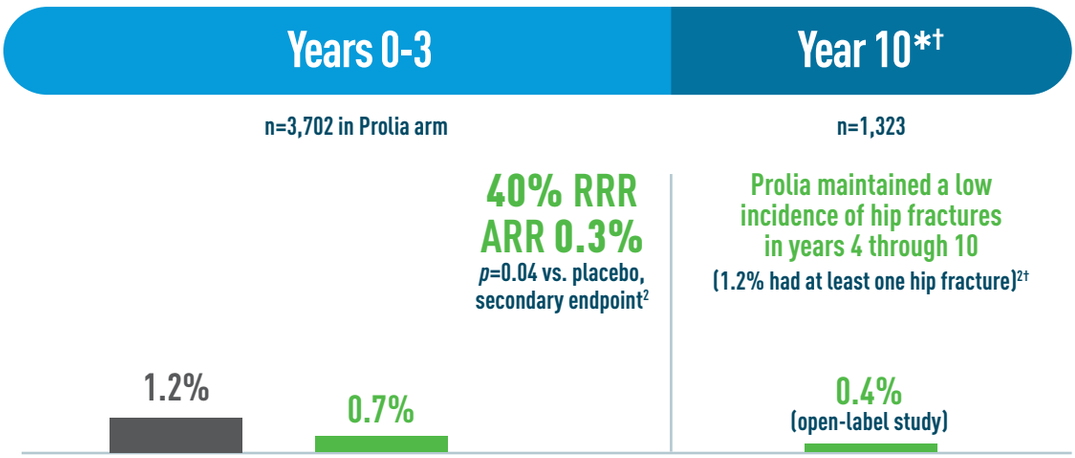
Pr prolia® denosumab injection

Fracture incidence with Prolia treatment over 10 years in postmenopausal osteoporosis

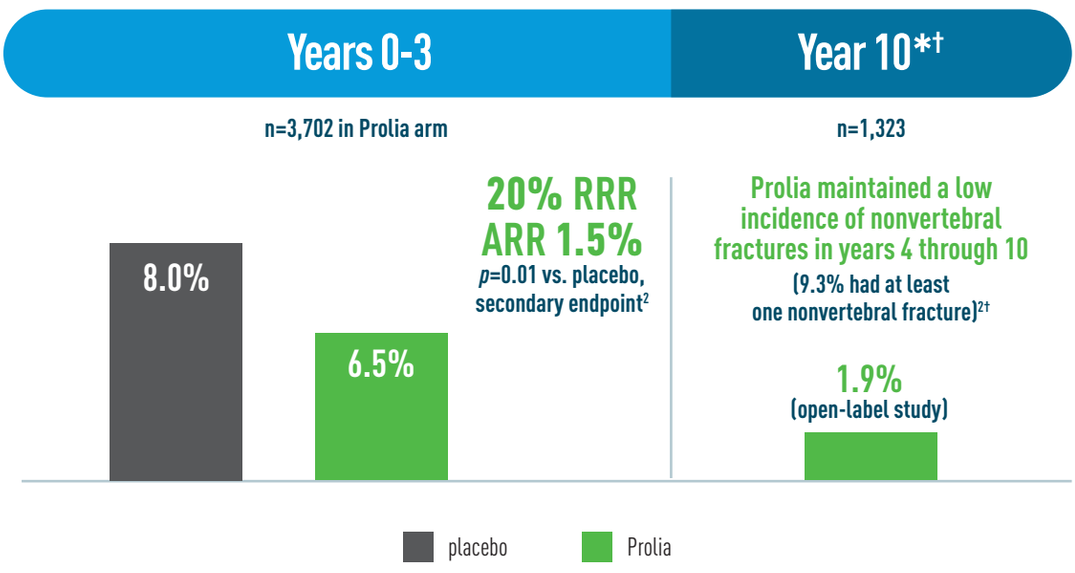
New vertebral fractures



Hip fractures



Nonvertebral fractures



ARR=absolute risk reduction; BMD=bone mineral density; RRR=relative risk reduction

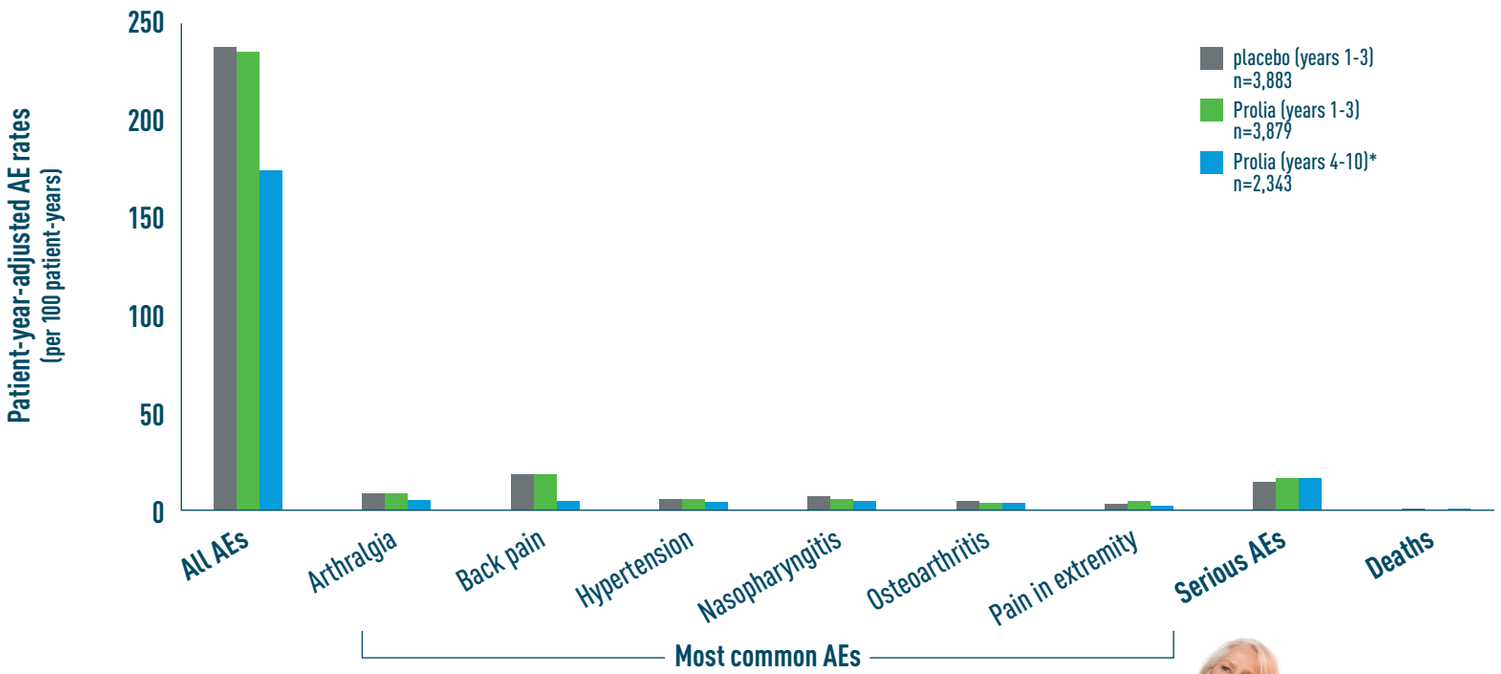
* Annualized yearly subject incidence.

† 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 BMD 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.[2]

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

OVERALL ADVERSE EVENTS[2]



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)[2]

* 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.[2]

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 of the study, women received Prolia for up to 10 years. Subjects were between the ages of 60 and 91 years and had BMD 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.[2]

Pr prolia® denosumab injection

Pr prolia® denosumab injection

Clinical use:

Prolia is not indicated for use in pediatric patients.

Contraindications:

- Hypersensitivity to the drug or any ingredient in the formulation, including any non-medicinal ingredient or component of the container. 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 that Prolia may cause fetal harm when administered to a pregnant woman and to use effective contraception during therapy and for at least 5 months after the last dose of Prolia.

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, including severe cases; clinical monitoring of calcium levels is recommended; follow standard medical care guidelines for signs and symptoms
- 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
- Hypersensitivity vasculitis
- Drug reaction with eosinophilia and systemic symptoms (DRESS)
- Musculoskeletal pain, including severe cases

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. Data on file. Amgen Canada Inc. **2.** Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., December 9, 2020.

1
60 mg
SC injection
every
6
months

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Fax 1-877-776-1022
Visit our website at Prolia.ca

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REVIEWED BY PAAB

MEMBER OF INNOVATIVE MEDICINES CANADA

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