

Osteoporosis Products Available in Canada for the Treatment and Prevention of Postmenopausal Osteoporosis



Physician Desk Reference

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THE SOCIETY OF
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Assessing Risk

The goals of osteoporosis management includes assessment of fracture risk and prevention of fracture and height loss. A Bone Mineral Density (BMD) test is only one part of assessing a woman's risk for osteoporosis.

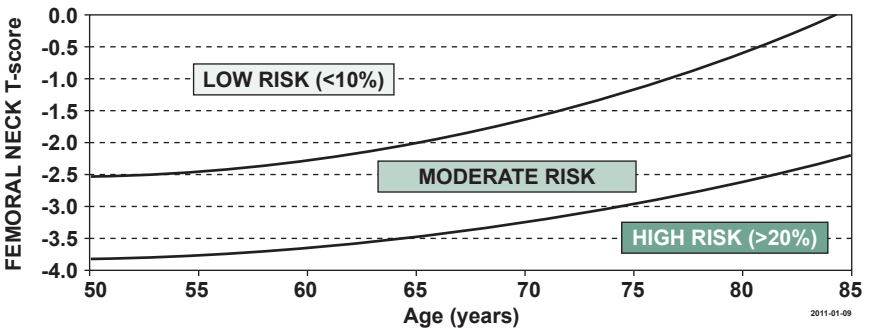
CAROC

Osteoporosis Canada recommends that fracture risk be determined using the 2005 Canadian Association of Radiologists/Osteoporosis Canada (CAROC) document which can be viewed at osteoporosis.ca.

Key risk factors to assess fracture risk

- Sex
- Age
- BMD
- Fragility fracture after age 40
- Recent prolonged systemic glucocorticoid use (≥ 3 mos in the prior year of a prednisone equivalent ≥ 7.5 mg daily)

Assessment of Basal 10-year Fracture Risk – Women



FRAX

The World Health Organization has also developed the FRAX tool to calculate fracture risk at the hip or for a major fragility fracture (spine, hip, forearm or shoulder) over the following 10 years. It is based on the BMD at the femoral neck as well as the following important risk factors for fracture: age, weight, height, prior fragility fracture, parental history of hip fracture, smoking status, use of prednisone, presence of rheumatoid arthritis, presence of a secondary cause for osteoporosis such as hyperthyroidism, alcohol intake 3 or more per day. Treatment is recommended if the 10 year fracture risk at the hip is $\geq 3\%$ or for a major osteoporotic fracture is $\geq 20\%$.

Risk factors are additive, meaning that the more risk factors, the greater the risk of developing osteoporosis. Assessing risk factors can help identify those that can change. Some of these factors are a result of heredity; others are lifestyle factors. By making changes to lifestyle, patients can improve their bone health and lower their risk of developing osteoporosis. (Osteoporosis Canada, 2011)

Lifestyle Strategies for Osteoporosis Management

SOGC recommendations on lifestyle strategies to manage osteoporosis

“Early assessment of skeletal health and then initiation of Calcium and Vitamin D supplementation and an exercise program are essential in the prevention and treatment of osteoporosis....”¹

Osteoporosis Canada recommendations on lifestyle interventions

“For all patients, regular weight-bearing, balance and strengthening exercises, smoking cessation, and optimization of total (dietary and supplements) Calcium and Vitamin D intake are recommended. For patients at risk of falls, fall-prevention strategies should be implemented.”³

Regular exercise ³	<ul style="list-style-type: none">• Resistance training appropriate for the individual’s age and functional capacity and/or weight-bearing aerobic exercises• Exercises to enhance core stability• Exercises that focus on balance or on balance and gait training
Calcium & Vitamin D ³	<ul style="list-style-type: none">• Total daily intake of elemental Calcium (through diet and supplements):<ul style="list-style-type: none">- Adults 19 to 50: 1,000 mg- Adults 50+: 1,200 mg• Vitamin D daily supplementation:<ul style="list-style-type: none">- Adults under age 50 without osteoporosis or conditions affecting vitamin D absorption: 400-1,000 IU- Adults 50+: 800-2,000 IU
Diet / Nutrition ¹	<ul style="list-style-type: none">• Limit coffee intake (<4 cups/day)• Limit alcohol intake (<3 beverages/day)
Smoking cessation should be strongly advised ^{1,3}	

Prescribing Therapies for Postmenopausal Osteoporosis

For individuals with postmenopausal osteoporosis, there is now a variety of drug treatments available. This guide was developed to assist physicians in optimizing treatment decisions by summarizing some of the key information about all drug treatments currently available in Canada. For complete information about the individual treatments in this guide, please consult the respective product monographs at <http://webprod3.hc-sc.gc.ca/dpd-bdpp>.

First-line Medications for Postmenopausal Osteoporosis Treatment and/or Prevention

SOGC recommendations on treatment of osteoporosis:

“The goals of osteoporosis management include assessment of fracture risk and prevention of fracture and height loss. Pharmacologic therapy is recommended if the 10-year absolute fracture risk is greater than 20% (high). In those with a moderate risk, management decisions should be individualized ... for those at high fracture risk, pharmacological intervention is advised.”¹

Bisphosphonates

Product/ Manufacturer	Active Ingredient	Dosage / Strength and Administration	Clinical Indication(s)
ACLASTA Novartis Pharmaceuticals Canada Inc.	Zoledronic acid	IV 5 mg / 100 mL infused over ≥15 minutes (Once yearly)	• Treatment of osteoporosis in postmenopausal women
ACTONEL Warner Chilcott Canada Co.	Risedronate sodium	Tablet <i>Treatment of postmenopausal osteoporosis:</i> 5 mg (Daily) or 35 mg (Once weekly) 150 mg (Once monthly) <i>Prevention of postmenopausal osteoporosis:</i> 5 mg (Daily) or 35 mg (Once weekly)	• Treatment and prevention of osteoporosis in postmenopausal women
ACTONEL DR Warner Chilcott Canada Co.	Risedronate sodium (delayed release)	Tablet <i>Treatment of postmenopausal osteoporosis:</i> 35 mg (Once weekly)	• Treatment of osteoporosis in postmenopausal women
FOSAMAX Merck Canada Inc.	Alendronate sodium	Tablet 70 mg (Once weekly)	• Treatment and prevention of osteoporosis in postmenopausal women
FOSAVANCE 2800 Merck Canada Inc.	Alendronate sodium / cholecalciferol (vitamin D ₃)	Tablet 1 tablet (70 mg/2,800 IU vitamin D ₃) (once weekly)	• Treatment of osteoporosis in postmenopausal women
FOSAVANCE 5600 Merck Canada Inc.	Alendronate sodium / cholecalciferol (vitamin D ₃)	Tablet 1 tablet (70 mg/5,600 IU vitamin D ₃) (once weekly)	• Treatment of osteoporosis in postmenopausal women

Selective Estrogen Receptor Modulator (SERM)

Product/ Manufacturer	Active Ingredient	Dosage / Strength and Administration	Clinical Indication(s)
EVISTA Eli Lilly Canada Inc.	Raloxifene hydrochloride	Tablet 60 mg (Daily)	<ul style="list-style-type: none"> • Treatment and prevention of osteoporosis in postmenopausal women

RANK Ligand Inhibitor

Product/ Manufacturer	Active Ingredient	Dosage / Strength and Administration	Clinical Indication(s)
PROLIA Amgen Canada Inc.	Denosumab	Subcutaneous injection 60 mg in a single use prefilled syringe (Once every 6 months)	<ul style="list-style-type: none"> • 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.

Bone Formation Agent

Product/ Manufacturer	Active Ingredient	Dosage / Strength and Administration	Clinical Indication(s)
FORTEO Eli Lilly Canada Inc.	Teriparatide (recombinant human parathyroid hormone)	Subcutaneous injection 20 mcg (Daily) <i>The maximum lifetime exposure for an individual patient is 24 months</i>	<ul style="list-style-type: none"> • Treatment of postmenopausal women with severe osteoporosis who are at high risk of fracture or who have failed or are intolerant to previous osteoporosis therapy

First-line Hormone Therapy Products for Postmenopausal Osteoporosis Treatment and/or Prevention

SOGC supports the North American Menopause Society statement on Hormone Therapy:

“Recent data support the initiation of HT around the time of menopause ... to treat or reduce the risk of certain disorders, such as osteoporosis or fractures in selected postmenopausal women.”²

Hormonal Therapy: Oral Tablets

Product/ Manufacturer	Type of Hormone	Dosage / Strength and Administration	Clinical Indication(s)
ESTRACE Shire Canada Inc.	17β-Estradiol	Tablet 0.5mg 1 mg 2 mg (Daily)	<ul style="list-style-type: none"> • Adjunct to other therapeutics for the prevention of osteoporosis • Symptomatic relief of menopausal symptoms
femHRT Warner Chilcott Canada Co.	Ethinyl estradiol (EE) Norethindrone acetate (NETA)	Tablet 5 µg EE + 1 mg NETA (Daily)	<ul style="list-style-type: none"> • Prevention of osteoporosis • Relief of menopausal and postmenopausal symptoms • Symptomatic treatment of vulvar and vaginal atrophy associated with menopause
PREMARIN Pfizer Canada Inc.	Conjugated equine estrogens	Tablet 0.3 mg 0.625 mg 1.25 mg (Daily)	<ul style="list-style-type: none"> • Prevention of osteoporosis • Relief of menopausal and postmenopausal symptoms • Hypoestrogenism due to hypogonadism • Atrophic vaginitis • Vulvar atrophy
C.E.S. Valeant Canada Ltd.	Conjugated estrogens	Tablet 0.3 mg 0.625 mg 0.9 mg 1.25 mg (Daily)	<ul style="list-style-type: none"> • Treatment and prevention of osteoporosis • Relief of menopausal and postmenopausal symptoms • Hypoestrogenism due to hypogonadism • Atrophic vaginitis

Hormonal Therapy: Transdermal (Patches)

Product/ Manufacturer	Type of Hormone	Dosage / Strength and Administration	Clinical Indication(s)
CLIMARA Bayer Inc.	17 β -Estradiol	Patch 0.025 mg 0.05 mg 0.075 mg 0.1 mg (Once weekly)	<ul style="list-style-type: none"> • Prevention of osteoporosis (0.05, 0.075 and 0.1 mg only) • Relief of menopausal and postmenopausal symptoms
ESTRADERM Novartis Pharmaceuticals Canada Inc.	17 β -Estradiol	Patch 0.025 mg 0.1 mg (Twice weekly)	<ul style="list-style-type: none"> • Prevention of osteoporosis • Relief of menopausal and postmenopausal symptoms
ESTRADOT Novartis Pharmaceuticals Canada Inc.	17 β -Estradiol	Patch 0.025 mg 0.0375 mg 0.05 mg 0.075 mg 0.1 mg/day (Twice weekly)	<ul style="list-style-type: none"> • Prevention of osteoporosis • Relief of menopausal and postmenopausal symptoms

Other Antiresorptive for Postmenopausal Osteoporosis Treatment and/or Prevention

Product/ Manufacturer	Active Ingredient	Dosage /Strength and Administration	Clinical Indication(s)
MIACALCIN Novartis Pharmaceutical Canada Inc.	Synthetic calcitonin (salmon)	Nasal spray 1 actuation/spray (200 IU or 0.2 mcg) to alternating nostrils (Once daily)	<ul style="list-style-type: none"> • Treatment of osteoporosis >5 years postmenopause with low bone mass relative to healthy premenopausal women

References

1. Society of Obstetricians and Gynaecologists of Canada. Menopause and Osteoporosis Update 2009. J SOGC 2009; 31(1): S1-S46.
2. North American Menopause Society. Estrogen and progestogen use in postmenopausal women: 2010 position statement of The North American Menopause Society. Menopause 2010; 17(2): 242-55.
3. Papaioannou A, et al. 2010 Clinical practice guidelines for the diagnosis and management of osteoporosis in Canada: summary. CMAJ 2010; 182(17): 1864-73.
4. Health Canada Product Monographs. Available: <http://webprod3.hc-sc.gc.ca/dpd-bdpp> (accessed September 2011).

**For more information
on women's health issues
consult:**

sogc.org

menopauseandu.ca

sexualityandu.ca

endometriosisinfo.ca

hpvinfo.ca

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780 promenade Echo Drive, Ottawa, Ontario K1S 5R7
Tel/Tél.: 1 800 561-2416 or/ou (613) 730-4192 Fax/Télé.: (613) 730-4314 **www.sogc.org**