

Super Calcium with Vitamin D 650 mg/400 IU Tablet



Product Summary:

Osteoporosis is a disease in which bone mass loss and deterioration of bone tissue occurs. This disease affects more than 2 million Canadians – women and men alike.¹ Calcium and vitamin D help in the development and maintenance of bones and teeth. Calcium intake, when combined with sufficient vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis. Vitamin D also plays an important role in maintaining normal calcium and phosphorus levels

Properties/Uses:

The claim as approved by *Natural Health Products Directorate* (NHPD): Helps in the development and maintenance of bones and teeth. Calcium intake, when combined with sufficient vitamin D, a healthy diet and regular exercise, may reduce the risk of developing osteoporosis.



MUSCULAR
& SKELETAL



Pharmacology:

3 Calcium and vitamin D help in the development and maintenance of bones and teeth especially in childhood, adolescence and young adulthood. Calcium supplementation, in combination with vitamin D supplementation, addresses osteoporosis prevention and treatment.

Osteoporosis Canada states that 1 in 4 women and 1 in 8 men over the age of 50 have osteoporosis.¹ The best defense against osteoporosis in the senior years is thought to be the attainment of maximal bone mineral density in the early life years before 20-25. Both male and female teenagers and young adults should focus on early maximal bone mineral density.

Calcium intake provides strong bone development during the younger years and the acquired bone density needed to get us through our latter years without osteoporosis, which causes bones to become brittle and fragile. Adequate, lifelong dietary calcium intake is necessary to reduce the risk of osteoporosis—a disorder principally due to an imbalance in the bone remodeling action of osteoclast cells that break down bone, and osteoblast cells that build up new bone. This disorder is not principally due to a lack of calcium, but to an imbalance in the bone remodeling actions of the osteoclast cells that break down bone, and the osteoblast cells that build up new bone. Remodeling imbalance presents a wider therapeutic issue that mineral supplementation cannot in itself address. However, achieving optimal mineral conditions is a critical step. Other factors like lifestyle or hormonal therapy will address remodeling imbalance.

All calcium deficiencies if uncorrected will lead to bone disorders, especially in growing children, but not all cases of osteoporosis are the direct result of dietary calcium deficiency. Other considerations are important beyond calcium, and life style is central. The typical North American diet has the potential for causing excessive bone calcium “mobilization” that can lead to calcium wastage via urine excretion. High phosphate intake via meats and soft drinks, high sugar intake, and excessive plasma amino acid concentrations from excessive protein intake call for calcium buffering, represent chronic drains on calcium bone density.

Two other important lifestyle factors that influence the mineral density of bones are exercise and smoking. Many adults who work in sedentary jobs stop exercising in meaningful ways early in life. Yet, daily minimal weight-bearing exercise is able to drive bone formation, assuming dietary needs are met. Smoking is thought to ultimately lead to the potential for lower blood pH due to compromised CO₂ venting in the lungs, thus allowing higher levels of carbonic acid to accumulate in the blood. Accordingly, more bone minerals will be mobilized to buffer the blood.

Part of the problem in curbing the incidence of osteoporosis is a widespread singular focus on calcium, with little or no emphasis on magnesium and vitamin D, and often only lip service to other critical mineral factors and meaningful exercise.

Avoiding osteoporosis is much more complex than simply increasing calcium intake, or even relying on appropriate supplementation alone. Exercise and meaningful reductions in calcium wastage are central to maintaining optimal conditions for arresting bone decline. It is important to realize that osteoporosis is an infrequent disease in the so called third world, where calcium supplementation, and milk consumption for that matter, is virtually non-existent and daily dietary calcium intake is typically below the average intake of North Americans.² However, the level of weight-bearing exercise is consistently higher.





Those seeking to arrest or reverse osteoporosis should be encouraged to supplement with magnesium at a ratio of 2 parts calcium and 1 part magnesium. Magnesium appears to enhance calcium crystal size and shape, beneficially influencing crystal strength, and therefore, bone strength.²

Supplementation with vitamin D is used for the treatment and prevention of rickets in children and osteomalacia in adults.³ Vitamin D₃ (cholecalciferol) is the designation for the form of vitamin D produced in the skin, from cholesterol through the direct action of sunlight on the skin. Vitamin D₃ is essentially inactive until biotransformed into 25-hydroxy-vitamin D₃ in the liver, becoming five times more active than D₃, and then into 1,25-dihydroxy-vitamin D₃ in the kidneys, becoming ten times more active than D₃.⁴ Dietary and supplemental vitamin D₃ is oil soluble and can only be absorbed via oil absorption, making it necessary for D₃ supplementation to occur with fat/oil containing meals. Age-related decline in fat/oil absorption is a factor in diminished D₃ absorption, and clinically determined D₃ deficits may be required to adequately compensate in the treatment of osteoporosis.

Vitamin D performs three indispensable functions in developing and maintaining bone mineral density: (1) It facilitates dietary or supplemental calcium absorption from the intestines; (2) It decreases urinary calcium losses due to normal kidney filtration; and (3) It facilitates the incorporation of calcium into the bones.

Many consumers and physicians fail to emphasize vitamin D₃ supplementation in bone health enhancement. Those with diagnosed thinned bones or full-blown osteoporosis, can safely increase their calcium handling efficiencies with 800 to 1000 IUs per day. Even a subtle protracted deficiency of vitamin D₃ leads to increased risk of bone loss over time and osteoporosis fractures.⁵ Numerous studies document that up to 80% of all hip fracture patients may exhibit vitamin D deficiency.⁶ There is a growing clinical recognition of vitamin D deficiency in the general population, leading to the conclusion that current levels of so-called adequate intake are too low.^{5,7-9} Separate clinical investigations using 700 and 800 IUs instead of the usual 400 IUs have demonstrated lower hip fracture rates compared to placebo.⁹ The omission of vitamin D₃ supplementation by those with thinned bones or full-blown osteoporosis is a strategic error in judgement by physician and patient. The margin of safety is substantial for vitamin D, with prolonged daily supplementation with 10000 IUs being free of adverse effects, allowing an easy comfort level with 800 to 1000 IUs per day for adult bodies.¹⁰ Other nutritional factors are known to participate in bone formation and renewal, such as Vitamin K, Manganese, Folic Acid, Boron, Vitamin B-6, Zinc, Strontium, Copper, Silicon, and Vitamin C. These can be obtained in a diet of fruit and vegetables and whole grains, as well as supplementing.

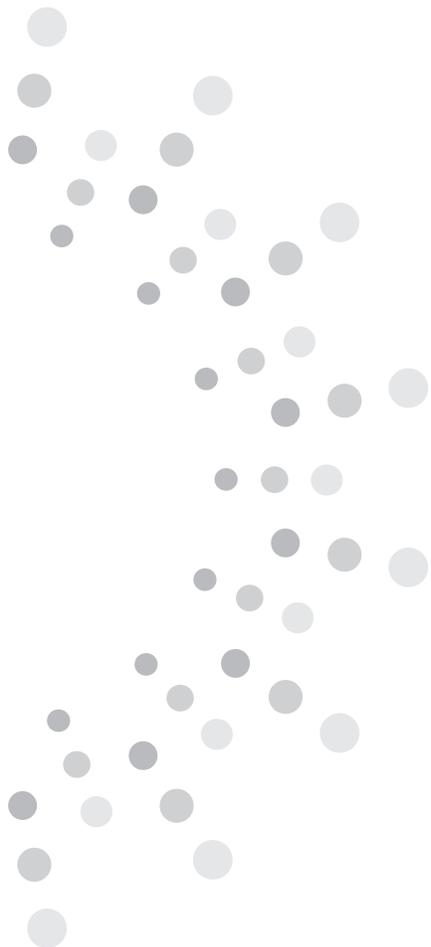
Vitamin D supplementation is especially important for the elderly because their vitamin D production abilities have declined. It is also important for people with limited sun exposure, people living in northern latitudes and dark-skinned people. To minimize health risks associated with UVB radiation exposure, while maximizing Vitamin D benefits, supplementation combined with small amounts of sun exposure is the recommended way to assure optimum levels of vitamin D.¹¹





Calcium and vitamin D are important to more than just bone and tooth health. Calcium supplementation has also been helpful in cases of salt-sensitive high blood pressure, as well as in pregnancy induced high blood pressure.^{4,12,13} Vitamin D may be useful in people with a history of cancer or with a family history of cancer, working as a risk reducer of cancer through vitamin D-dependent cellular differentiation. Furthermore, recent studies suggest a link between vitamin D deficiency and upper respiratory tract infections.¹⁴

A recent University of Auckland study published in the British Medical Journal suggested that calcium supplementation was associated with an increased risk of cardiovascular events.¹⁵ This is a controversial study whose findings are still being debated.¹⁶ The key to nutrient supplementation is balance. Calcium and vitamin D are both important in osteoporosis prevention and treatment; however, other nutritional factors are known to participate in bone formation and renewal, such as Vitamin K, Manganese, Folic Acid, Boron, Vitamin B-6, Zinc, Strontium, Copper, Silicon, and Vitamin C. These can be obtained in a diet of fruit and vegetables and whole grains, as well as supplementing. Individuals concerned about their calcium intake should consult their physician.





Manufactured product information:

Manufacturer:

WN Pharmaceuticals Ltd.

Size/UPC:

120's 7 77747 10332 4

NPN:

80026707

Expiry Date:

36 months from date of manufacture

Active Ingredients:

Each tablet contains:

Calcium (Carbonate, Citrate, Fumarate, Malate, Succinate).....650 mg

Vitamin D3 (Cholecalciferol)..... 10 mcg (400 IU)

Non-Medicinal Ingredients (in descending order):

Microcrystalline cellulose, croscarmellose sodium, coating (carbohydrate gum, glycerin), stearic acid, magnesium stearate, silica.

Appearance:

White to off white, oval bisect clear coated tablet.

Packaging:

300 cc white round bottle with safety seal under a 45 mm white induction sealed cap with vented interior seal and a label applied to the bottle. Lot number and expiry date are printed on the label applied to the exterior of the bottle.

Storage:

Store in tightly sealed container in a cool, dry place, protected from light and humidity.





Dose:

According to the NHPD for children and adults, the appropriate dosage of calcium is 65-1,500 mg per day.¹⁷

According to the NHPD for adults, the appropriate dosage of vitamin D is 0.8-25 mcg per day.¹⁷ The recommended dosage for children is 0.2-25mcg/day. However, many organizations and clinical trials suggest that higher dosages are appropriate.

Directions:

(Adults): 1– 2 tablets daily, a few hours before or after taking other medications, or as recommended by a physician.

Caution:

The caution as approved by Natural Health Products Directorate (NHPD): KEEP OUT OF THE REACH OF CHILDREN. STORE AT ROOM TEMPERATURE IN A DARK, DRY PLACE. DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

Deficiency Symptoms:

The bones and teeth contain greater than 99% of the calcium in the human body.¹⁸ Calcium deficiency can lead to reduced bone density resulting in rickets, osteomalacia or osteoporosis. A deficiency can also lead to muscle cramps.

Vitamin D deficiency is characterized by inadequate mineralization or demineralization of the skeleton. In children, this deficiency can result in rickets; in adults, it can result in osteomalacia. In addition, the secondary hyperparathyroidism associated with vitamin D deficiency enhances mobilization of calcium from the skeleton, resulting in porotic bone. It is well recognized that vitamin D deficiency causes abnormalities in calcium and bone metabolism.¹⁹ Vitamin D deficiency is linked to an increased risk of falls.³

Drug Interactions/Contraindications:

In older osteoporotic patients with compromised fat absorption, the optimal daily intake of fat soluble vitamin D should be clinically determined to insure that disease modifying absorption of dietary calcium, renal re-absorption of calcium, and vitamin D-dependent bone incorporation of calcium is occurring.



Boron and vitamin K cannot be supplemented in Canada but are key nutrients profoundly relevant to bone health. However, both of these nutrients can be supplied in a diet that emphasizes fruits and vegetables, especially green leafy vegetables and apples, which can contain as much as 3 mg of boron in the apple skin. If this is unlikely to happen on a consistent basis, regular use of a dehydrated plant food supplement should be recommended.

Boron depletion in postmenopausal women contributes to urinary excretion of calcium and magnesium, and depressed serum concentrations of estrogen and testosterone, both hormones being important to bone remodeling.⁴

Calcium

Calcium absorption is dependent on the presence of adequate vitamin D.

The use of calcium without also supplementing magnesium may be a risk factor for developing magnesium depletion over time.

Quinolones and tetracyclines combine with calcium, magnesium or other minerals. Concurrent use will render the antibiotics less effective. Minerals should be taken at least two hours apart from these antibiotics. Used long term, these antibiotics may produce mineral deficiencies.²⁰

Loop diuretics may cause the loss of calcium and magnesium from the body, frustrating efforts to address osteoporosis.²⁰

Thiazide diuretics cause mineral losses, including calcium and magnesium. Long term use could deplete the body of these and other minerals. Since many of those using thiazides could also be osteoporotic, supplementation of minerals may be necessary.²⁰

Corticosteroids interfere with calcium absorption and metabolism. Long term use may contribute to or exacerbate osteoporosis.²⁰

Etidronate (Didronel) reacts with calcium and magnesium interfering with its absorption, if the respective dosing are not separated by at least two hours. However, this drug also alters vitamin D metabolism so that calcium deficiencies may result.²⁰

Calcium interferes with iron absorption.²⁰

Isoniazid alters vitamin D metabolism with possible reduction in calcium absorption. Supplementation with vitamin D at the optimal dose for individual needs should be advised.²⁰

High doses of magnesium, zinc, fiber, and oxalates interfere with calcium absorption.²⁰

Caffeine, alcohol, phosphates (soft drinks, meat, many can goods), protein (amino acids), sodium, and sugar lead to increased calcium excretion.²⁰

Digitalis may adversely affect magnesium status. Magnesium depletion is associated with an adverse heart impact, including arrhythmias and coronary spasms.^{21,22}

Patients with hyperparathyroidism or cancer should not supplement with calcium unless directed by a physician.¹⁸

Supplementing with calcium in some people may increase the risk of forming calcium kidney stones. Co-use of at least half as much magnesium lowers the risk of kidney stones.¹⁸





Vitamin D

Vitamin D3 is oil soluble and can be absorbed only via fat/oil absorption, making mealtime dosing the best time to supplement. The higher the dose of vitamin D3, the greater is the need of fat or oil in the meal.

Use of Olestra has been reported to diminish absorption of the fat-soluble vitamins, A, D, E, and K.

Magnesium supplementation is required to convert vitamin D2 to D3.

Bile acid sequestrants like Cholestyramine, corticosteroids, Dilantin, barbiturates, Phenobarbital, etidronate, tuberculosis drugs, and mineral oil interfere with vitamin D absorption and /or metabolism.^{4,20}

Toxicity/Adverse Reactions:

Calcium supplements are usually well tolerated in daily dosages up to 2000 mgs. Higher intakes may contribute to kidney stone formation and soft-tissue calcium deposits.^{4,23} However, magnesium supplementation reduces the risk for kidney stone formation, especially magnesium citrate, increasing the solubility of calcium in urine formation.^{2,4} Using more than 2000 mg per day is unlikely to make a significant clinical contribution unless deemed to be warranted by a clinician.

Vitamin D toxicity is not widely reported in North America. Prolonged intake of up to 2400 IUs per day has a wide margin of safety.⁹ However, in practical terms, most supplementation does not call for more than 1000 IUs per day, unless prescribed by a physician. Vitamin D toxicity is manifested as exaggerated calcium blood levels that can lead to calcium deposits in joints and internal organs, and cause kidney stones.⁴



Allergen Content/Ingredient Sensitivity:

| NO | YES |
|--------------------------|------------------------|
| Artificial Color | Corn Products |
| Artificial Flavor | Starch/Modified Starch |
| Artificial Sweeteners | |
| Egg Products | |
| Fish | |
| Gluten | |
| Hydrolyzed Plant Protein | |
| Lecithin | |
| Milk Products | |
| Peanuts | |
| Preservatives | |
| Sesame Products | |
| Shellfish | |
| Tartrazine | |
| Tree Nuts | |
| Wheat Products | |
| Yeast | |
| | |

NOT ACCEPTABLE FOR THE FOLLOWING DIETARY RESTRICTIONS:

Free of animal products

Kosher





References:

1. Osteoporosis Canada [www.osteoporosis.ca]
2. Gaby AR. Preventing and Reversing Osteoporosis. Prima Publishing, Rocklin CA, 1994.
3. Natural Medicine Comprehensive Database (NMCD), Vitamin D Monograph, Accessed December 1, 2009 [[Available from: http://www.naturaldatabase.com/](http://www.naturaldatabase.com/)]
4. Murray MT. Encyclopedia of Nutritional Supplementation. Prima Publishing, Rocklin CA, 1996.
5. Compston JE. Vitamin D Deficiency: time for action (editorial). *British Medical Journal* 1998;317:1466-1467.
6. Brown SE. Better Bones, Better Body. Keats Publishing, New Canaan CT, 1996.
7. Vieth R, Bischoff-Ferrari H, Boucher BJ, et al. The urgent need to recommend an intake of vitamin D that is effective (editorial). *Am J Clin Nutr* 2007;85:649-50.
8. Thomas MK. Hypovitaminosis D In Medical Inpatients. *New England Journal Of Medicine* 1998;338(12):777-783.
9. Utiger RD. The Need For More Vitamin D (editorial). *New England Journal Of Medicine* 1998;338(12):828-829.
10. Vieth R. Vitamin D and cancer mini-symposium: the risk of additional vitamin D. *Ann Epidemiol* 2009;19:441-445.
11. Stechschulte SA, Kirsner RS, Federman DG. Vitamin D: bone and beyond, rationale and recommendations for supplementation. *Am J Med* 2009 Sep;122(9):793-802.
12. Belizan JM, et al. Calcium supplementation to prevent hypertensive disorder of pregnancy, *New Engl J Med*. 1991; 325: 1399-1405.
13. Knight KB, et al. Calcium supplementation on normotensive and hypertensive pregnant women, *Amer J Clin Nutr*. 1992; 55: 891-895.
14. Ginde AA, Mansbach JM, Camargo Jr CA. Association between serum 25-hydroxyvitamin D level and upper respiratory tract infection in the Third National Health Nutrition Examination Survey. *Arch Intern Med* 2009 Feb;169(4):384-390.
15. Bolland MJ, Grey A et al. Calcium supplements with or without vitamin D and risk of cardiovascular events: reanalysis of the Women's Health Initiative limited access data set and meta-analysis. *Brit Med J* 2011; 342: d2040.
16. Abrahamsen B, Sahota O. Do calcium plus vitamin D supplements increase cardiovascular risk? *Brit Med J* 2011; 342: d2080.
17. Health Canada, Multi-vitamin/Mineral Supplements Monograph, Accessed October 18, 2011 [[Available from: http://www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)]



18. Natural Medicine Comprehensive Database (NMCD), Calcium Monograph, Accessed November 12, 2010 [Available from: <http://www.naturaldatabase.com/>]
19. Institute of Medicine Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. Dietary reference intakes: calcium, phosphorus, magnesium, vitamin D, and fluoride. Washington, D.C.: National Academy Press, 1997
20. Graedon J, Graedon T. Deadly Drug Interactions. St. Martin Griffin, New York NY, 1995.
21. Teo KK, et al. Role of magnesium in reducing mortality in acute myocardial infarction: A review of the evidence, *Drugs*. 1993; 46: 347-359.
22. Turlapaty P, et al. Magnesium deficiency produces spasms of coronary arteries: Relationship to etiology of sudden ischemic heart disease. *Science*. 1980; 208: 199-200.
23. Whitaker, Julian. Dr Whitaker's Guide to Natural Healing. Prima Publishing, Rocklin, CA, 1995

Revision #00

