

## Vitamin D (>1,000-2,500 IU)

Source: [https://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/atReq?atid=vitamin.d.hd\(=eng](https://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/atReq?atid=vitamin.d.hd(=eng)

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VITAMIN D (>1,000 - 2,500 IU) Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 60 ko) This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients. Notes Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion. The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant. Other Vitamin D claims from the Multi-vitamin/mineral Supplements monograph are intentionally excluded from this monograph, as products providing >1,000 IU of vitamin D per day are not recommended for general supplementation. Date July 23, 2021 This monograph is only applicable to single ingredient products and cannot be combined with any other monograph. Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper Name(s) Common Name(s) Source information Source ingredient(s) Vitamin D Vitamin D Vitamin D 2Ergocalciferol Vitamin D Vitamin D 3 Cholecalciferol References: Proper name: Sweetman 2015, IOM 2013, O'Neil 2013; Common names: Sweetman 2015, IOM 2013, O'Neil 2013; Source information: Sweetman 2015, IOM 2013, O'Neil 2013. Route of administration Oral Dosage form(s) This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document. Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Use(s) or Purpose(s) Helps to prevent vitamin D deficiency (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 1997). Vitamin D intake, when combined with sufficient calcium, a healthy diet and regular exercise may reduce the risk of developing osteoporosis in people with vitamin D deficiency (Kahwati et al. 2018; Shils et al. 2006; NIH 2001; Groff and Gropper 2000). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Table 2. Daily doses for high dose Vitamin D products Medicinal ingredient Minimum 1 Maximum 2 Vitamin D > 25 µg (> 1,000 IU\*) ≤ 62.5 µg (≤ 2,500 IU\*) 1 This value is based on the previous Prescription Drug List limit (HC 2020). 2 This value is based on the Prescription Drug List limit amended in 2021 (HC 2021). Notes The quantity of vitamin D per dosage unit must always be provided in micrograms (µg). Optional: \*International Units (IU) may be provided as additional quantity per dosage unit. Conversion factor: 1 IU of vitamin D = 0.025 µg cholecalciferol or ergocalciferol (IOM 2006). Direction(s) for use To be taken with an adequate intake of calcium. Duration(s) of use Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 6 months (BfR 2020). Risk information Caution(s) and warning(s) Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding. Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have kidney disorders (BfR 2020; NIH 2020). Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you take other vitamin D supplements, multivitamin supplements containing vitamin D, or products containing vitamin D analogues. Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you take any prescription medications including antacids, anticonvulsants, digoxin, cholestyramine, colestipol, mineral oil, steroids, statins or thiazide diuretics (BfR 2020; NNHPD 2021). 15-20 mcg (600-800 IU) of vitamin D per day is an adequate quantity for most individuals. Consult a health care practitioner/health care provider/health care professional/doctor/physician to determine if you would benefit from additional vitamin D before taking this product. Contraindication(s) Do not use this product if you have hypercalcemia and/or hypercalciuria (BfR 2020; NIH 2020). Known adverse reaction(s) Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if the following early symptoms of hypercalcemia occur: weakness, fatigue, drowsiness, headache, lack of appetite, dry mouth, metallic taste, nausea, vomiting, vertigo, ringing in the ears, lack of coordination and muscle weakness or if you develop any other symptom (BfR 2020; NIH 2020). Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health

Products Regulations (NHPR). Specifications The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPR. References cited BfR 2020: Vitamin D: consumption of high-dose food supplements is unnecessary; BfR Opinion No 035. [Accessed May 14, 2021]. Available from: <https://www.bfr.bund.de/cm/349/vitamin-d-consumption-of-high-dose-food-supplements-is-unnecessary.pdf>. Groff J, Gropper S. Advanced Nutrition and Human Metabolism, 3rd edition. Belmont (CA): Wadsworth/Thomson Learning; 2000. HC 2021: Health Canada's Prescription Drug List. [Accessed May 14, 2021]. Available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list.html>. HC 2020: Health Canada: Notice of Intend to Amend the Prescription Drug List: Vitamin D. [Accessed May 14, 2021]. Available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/notices-changes/notice-intent-vitamin-d.html>. IOM 2006: Institute of Medicine. Otten JJ, Pitz Hellwig J, Meyers LD, editors. Institute of Medicine. Dietary Reference Intakes: The Essential Guide to Nutrient Requirements. Washington (DC): National Academies Press; 2006. IOM 2003: Institute of Medicine. Committee on Food Chemicals Codex, Food and Nutrition Board, Institute of Medicine. Food Chemicals Codex, 5th edition. Washington (DC): National Academies Press; 2003. IOM 1997: Institute of Medicine. Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride. Washington (DC): National Academy Press; 1997. Kahwati LC, Weber RP, Pan H, Gourlay M, LeBlanc E, Coker-Schimmer M, Viswanathan M. Vitamin D, Calcium, or Combined Supplementation for the Primary Prevention of Fractures in Community-Dwelling Adults: Evidence Report and Systematic Review for the US Preventive Services Task Force. JAMA; 2018; 319(15):1600-1612. NIH 2020: National Institute of Health: Vitamin D Fact Sheet for Health Professionals. [Accessed May 14, 2021]. Available from: <https://ods.od.nih.gov/factsheets/VitaminD-HealthProfessional/> NIH 2015: National Institutes of Health. ChemIDplus advanced. Bethesda (MD): Specialized Information Services, U.S. National Library of Medicine, National Institutes of Health, Department of Health & Human Services. [Accessed May 14, 2021]. Available from: <https://chem.nlm.nih.gov/chemidplus/>. NIH 2001: National Institute of Health. Osteoporosis Prevention, Diagnosis, and Therapy. NIH Consensus Development Panel on Osteoporosis Prevention, diagnosis and therapy. JAMA; 2001; 17(1):1-36. NNHPD 2021. Natural and Non-Prescription Health Products Directorate. Internal evidence and HC's product monographs. O'Neil MJ, Smith A, Heckelman PE, Budavari S, editors. The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals, 15th edition. Whitehouse Station (NJ): Merck & Co., Inc.; 2013. Shils ME, Olson JA, Shike M, Ross AC, Caballero B, Cousins RJ, editors. Modern Nutrition in Health and Disease. 10th edition. Philadelphia (PA): Lippincott Williams & Wilkins; 2006. Sweetman SC, editor. 2015. Martindale: The Complete Drug Reference. London (GB): Pharmaceutical Press. [Accessed May 14, 2021]. Available from: <http://www.medicinescomplete.com>. Report a problem on this page Date modified: 2019-03-01

## MEDICINAL INGREDIENT(S)

Notes Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion. The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant. Other Vitamin D claims from the Multi-vitamin/mineral Supplements monograph are intentionally excluded from this monograph, as products providing >1,000 IU of vitamin D per day are not recommended for general supplementation. Date July 23, 2021 This monograph is only applicable to single ingredient products and cannot be combined with any other monograph. Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper Name(s) Common Name(s) Source information Source ingredient(s) Vitamin DVitamin DVitamin D2ErgocalciferolVitamin DVitamin D3Cholecalciferol

## DOSAGE FORM(S)

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

## DOSE(S)

Medicinal ingredient Minimum<sup>1</sup> Maximum<sup>2</sup> Vitamin D > 25 µg (> 1,000 IU\*) ≤ 62.5 µg (≤ 2,500 IU\*)

## RISK INFORMATION

Caution(s) and warning(s) Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding. Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have kidney disorders (BfR 2020; NIH 2020). Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you take other vitamin D supplements, multivitamin supplements containing vitamin D, or products containing vitamin D analogues. Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you take any prescription medications including antacids, anticonvulsants, digoxin, cholestyramine, colestipol, mineral oil, steroids, statins or thiazide diuretics (BfR 2020; NNHPD 2021). 15-20 mcg (600-800 IU) of vitamin D per day is an adequate quantity for most individuals. Consult a health care practitioner/health care provider/health care professional/doctor/physician to determine if you would benefit from additional vitamin D before taking this product. Contraindication(s) Do not use this product if you have hypercalcemia and/or hypercalciuria (BfR 2020; NIH 2020). Known adverse reaction(s) Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if the following early symptoms of hypercalcemia occur: weakness, fatigue, drowsiness, headache, lack of appetite, dry mouth, metallic taste, nausea, vomiting, vertigo, ringing in the ears, lack of coordination and muscle weakness or if you develop any other symptom (BfR 2020; NIH 2020).

## NON-MEDICINAL INGREDIENTS

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations (NHPR).

## STORAGE CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations (NHPR).

## SPECIFICATIONS

The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPID.

## REFERENCES

Route of administration Oral

Proper Name(s)	Common Name(s)	Source information
Source ingredient(s)		
Vitamin D	Vitamin DVitamin D2	Ergocalciferol
Vitamin DVitamin D3	Cholecalciferol	

Medicinal ingredient	Minimum <sup>1</sup>	Maximum <sup>2</sup>
Vitamin D	> 25 µg (> 1,000 IU*)	≤ 62.5 µg (≤ 2,500 IU*)