

NATURAL HEALTH PRODUCT

VITAMIN D (>1,000-2,500 IU)

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 ingredient.

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	<ul style="list-style-type: none"> • Vitamin D • Vitamin D₂ 	Ergocalciferol
	<ul style="list-style-type: none"> • Vitamin D • Vitamin D₃ 	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*)

¹This value is based on the previous Prescription Drug List limit (HC 2020).

²This 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 NHPID.

References cited

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