Notice: Prescription Drug List (PDL): Vitamin D

February 22, 2021

Our file number: 21-103221-458

The purpose of this Notice of Amendment is to notify that Health Canada has revised the listing of Vitamin D on the Prescription Drug List (PDL) to allow non-prescription status for products a) containing up to 62.5 µg or 2,500 International Units (IU)/dosage form for oral use; or b) with a maximum recommended daily oral intake of 2,500 IU. Only the Human part of the PDL was revised. Health Canada conducted a scientific review of Vitamin D against a set of established and publicly available criteria outlined in section C.01.040.3 of the *Food and Drug Regulations*.

The listing now reads:

Drugs containing any of the following	**Including (but not limited to)**	**Qualifier**	**Effective Date**

Drugs containing any of the following	Including (but not limited to)	Qualifier	Effective Date
Vitamin D	N/A	in oral dosage form containing more than 62.5 µg or 2,500 International Units of Vitamin D per dosage form, or where the largest recommended daily dosage shown on the label would result in the daily intake by that person of more than 62.5 µg or 2,500 International Units of Vitamin D	2021-02-24

Rationale

Health Canada has received requests from consumers, physicians and industry regarding potentially increasing the non-prescription vitamin D limit set out on the PDL. The Natural and Non-prescription Health Products Directorate (NNHPD) has also received various product license applications (PLAs) ranging from 2,000 IU to 10,000 IU of vitamin D per daily dose.

With the mounting interest from stakeholders, and given that the scientific evidence regarding supplemental vitamin D has evolved since 1997, Health Canada's Food Directorate undertook a safety assessment to determine whether sufficient safety information existed to support raising the maximum non-prescription vitamin D daily dose up to 2,500 IU (62.5 µg). According to the Food Directorate's review [1], 2,500 IU (62.5 µg) would provide a safe daily maximum dose of vitamin D in non-prescription supplements for healthy children 9 years and older, adolescents and adults.

It is important to note that the new maximum supplemental vitamin D daily dosage of 2,500 IU (62.5 µg) is not considered a safe dosage for all subpopulations. For children younger than 9 years of age, specific dosage recommendations will be addressed by NNHPD's Class III review of product licence applications to establish the approved conditions of use.

The Recommended Dietary Allowance (RDA) is the daily amount of a nutrient required to meet the needs of about 97.5% of the population. [2] Table 1.0 provides the RDA and Tolerable Upper Intake Level (UL) per day for Vitamin D for the different age groups:

Table 1.0 - The Dietary Reference Intakes for Vitamin D

Age group	Recommended Dietary Allowance (RDA) per day	Tolerable Upper Intake Level (UL) per day
Infants 0-6 months	400 IU (10 µg) *	1000 IU (25 µg)
Infants 7-12 months	400 IU (10 µg) *	1500 IU (38 µg)
Children 1-3 years	600 IU (15 µg)	2500 IU (63 µg)
Children 4-8 years	600 IU (15 µg)	3000 IU (75 µg)
Children and Adults 9-70 years	600 IU (15 µg)	4000 IU (100 µg)

*	Adequate Intake rather than Recommended Dietary Allowance.

Age group	Recommended Dietary Allowance (RDA) per day	Tolerable Upper Intake Level (UL) per day
Adults > 70 years	800 IU (20 µg)	4000 IU (100 µg)
Pregnancy & Lactation	600 IU (15 µg)	4000 IU (100 µg)

* Adequate Intake rather than Recommended Dietary Allowance.

There are additional vulnerable subpopulations, documented adverse effects, drug interactions, cautions, warnings, and contraindications beyond what is described in the present notice. These issues will be addressed by cautionary statements on the labels of high-dose vitamin D supplements when the need is identified during the mandatory premarket evaluation process.

Sponsors seeking market authorizations for high dose Vitamin D under the Natural Health Products Regulations (1,000 to 2,500 IU per dosage form, or dosage up to 2,500 IU per day) can submit a Class III product licence application (containing safety and efficacy evidence) to the Natural and Non-Prescription Health Products Directorate (NNHPD) for full assessment. Please refer to the Natural Health Products Management of Applications Policy (NHP MAP) for more information on the classes of Natural Health Product (NHP) applications and the application process. In addition, please refer to the Pathway for Licensing Natural Health Products Making Modern Health Claims guidance document for more information pertaining to evidence requirements linked to safety, efficacy and quality for NHP applications.

If needed, a pre-submission meeting can be scheduled with NNHPD prior to submitting an application. The purpose of a pre-submission meeting is to discuss the evidence required in support of a Class III application. Pre-submission meetings do not entail a full assessment by NNHPD of the evidence presented and, as such, the outcome of the meeting does not constitute a regulatory decision, nor will a regulatory decision be issued. A pre-submission meeting request must be submitted to the NNHPD Client Service Unit (hc.nnhpd-dpsnso.sc@canada.ca) no less than one month prior to the proposed meeting date. Please consult section 4.3 of the NHP MAP for more information.

Additional information on how Health Canada determines prescription status (or non-prescription status) is available in the Guidance Document: Determining Prescription Status for Human and Veterinary Drugs.

Should you have any questions on this amendment to the PDL please contact:

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Footnotes

1 Available upon request from: hc.publications-publications.sc@canada.ca

2 Vitamin D and Calcium: Updated Dietary Reference Intakes

Date modified:
2021-02-24