Guideline on Product Categorization

Reference Details

Vitamins & Elements

National Medicines regulatory Authority, Sri Lanka

Section: Borderline Products

NMRA/BP/BPEC/GLs/MV/CP/P15/2017

Recommended Dietary Allowances (DRAs) for Borderline Products

Vitamins

Life Stage Group	**Levels**	**Vitamin A** (µg/d)[a]	**Vitamin C** (mg/d)	**Vitamin D** (µg/d)[b, c]	**Vitamin E** (mg/d)[d]	**Vitamin K** (µg/d)	**Thiamin** (mg/d)	**Riboflavin** (mg/d)	**Niacin** (mg/d)[e]	**Vitamin B_6** (mg/d)	**Folate** (µg/d)[f]	**Vitamin B_{12}** (µg/d)	**Pantothenic Acid** (mg/d)	**Biotin** (µg/d)	**Choline** (mg/d)[g]
2-8 years	Maximum	400	30	5	7	15	0.5	0.5	6	0.5	160	0.9	2	8	250
	Minimum	200	15	2.5	3.5	7.5	0.25	0.25	3	0.25	80	0.45	1	4	125
	Therapeutic Level	>400	>30	>5	>7	>15	>0.5	>0.5	>6	>0.5	>160	>0.9	>2	>8	>250
	Tolerable Upper Intake Level (UL)	900	650	75	300	ND	ND	ND	15	40	400	ND	ND	ND	1.0g
9-18 years	Maximum	600	40	10	10	35	1.1	1	16	2	400	2.4	5	25	375
	Minimum	300	20	5	5	17.5	0.55	0.5	8	1	200	1.2	2.5	12.5	187.5
	Therapeutic Level	>600	>40	>10	>10	>35	>1.1	>1	>16	>2	>400	>2.4	>5	>25	>375
	Tolerable Upper Intake Level (UL)	2,800	1,800	100	800	ND	ND	ND	30	80	800	ND	ND	ND	3.0 g
>18	Maximum	500	65	6	22	55	1.2	1	14	1.3	400	2.4	5	30	550

years (Adults)	Minimum	250	32.5	3	11	22.5	0.6	0.5	7	0.65	200	1.2	2.5	15	275
	Therapeutic Level	>500	>65	>6	>22	>55	>1.2	>1	>14	>1.3	>400	>2.4	>5	>30	>550
	Tolerable Upper Intake Level (UL)	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5g
Life Stage Group	**Levels**	**Vitamin A** (µg/d)[a]	**Vitamin C** (mg/d)	**Vitamin D** (µg/d)[b, c]	**Vitamin E** (mg/d)[d]	**Vitamin K** (µg/d)	**Thiamin** (mg/d)	**Riboflavin** (mg/d)	**Niacin** (mg/d)[e]	**Vitamin B_6** (mg/d)	**Folate** (µg/d)[f]	**Vitamin B_{12}** (µg/d)	**Pantothenic Acid** (mg/d)	**Biotin** (µg/d)	**Choline** (mg/d)[g]
Pregnancy	Desirable level	800	55	10	10	55	1.4	1.4	18	1.9	600	2.6	6	30	-
	Tolerable Upper Intake Level (UL)	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5g
Lactating woman	Desirable level	500	70	10	10	55	1.5	1.6	17	2	500	2.8	7	35	-
	Tolerable Upper Intake Level (UL)	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5g

NOTE: This table (taken from the DRI reports, see www.nap.edu) presents Recommended Dietary Allowances (RDAs). An RDA is the average daily dietary intake level sufficient to meet the nutrient requirements of nearly all (97–98 percent) healthy individuals in a group. It is calculated from an Estimated Average Requirement (EAR).

If sufficient scientific evidence is not available to establish an EAR, and thus calculate an RDA, an AI is usually developed. For healthy breast-fed infants, an AI is the mean intake. The AI for other life stage and gender groups is believed to cover the needs of all healthy

individuals in the groups, but lack of data or uncertainty in the data prevent being able to specify with confidence the percentage of individuals covered by this intake.

a. As retinol activity equivalents (RAEs). 1 RAE = 1 μg retinol, 12 μg β-carotene, 24 μg α-carotene, or 24 μg β-cryptoxanthin. The RAE for dietary provitamin A carotenoids is two-fold greater than retinol equivalents (REs), whereas the RAE for preformed vitamin A is the same as RE.

b. As cholecalciferol. 1 μg cholecalciferol = 40 IU vitamin D (vitamin D, 1 IU= 0.025 μg cholecalciferol).

c. Under the assumption of minimal sunlight.

d. As α-tocopherol. α-tocopherol includes RRR-α-tocopherol, the only form of α-tocopherol that occurs naturally in foods, and the *2R*-stereoisomeric forms of α-tocopherol (*RRR*-, *RSR*-, *RRS*-, and *RSS*-α-tocopherol) that occur in fortified foods and supplements. It does not include the *2S*-stereoisomeric forms of α-tocopherol (*SRR*-, *SSR*-, *SRS*-, and *SSS*-α-tocopherol), also found in fortified foods and supplements (vitamin E, 1 IU=0.67 natural α-tocopherol).

e. As niacin equivalents (NE). 1 mg of niacin = 60 mg of tryptophan (an amino acid).

f. As dietary folate equivalents (DFE). 1 DFE = 1 μg food folate = 0.6 μg of folic acid from fortified food or as a supplement consumed with food = 0.5 μg of a supplement taken on an empty stomach.

g. Although AIs have been set for choline, there are few data to assess whether a dietary supply of choline is needed at all stages of the life cycle, and it may be that the choline requirement can be met by endogenous synthesis at some of these stages.

h. Because 10 to 30 percent of older people may malabsorb food-bound B_{12}, it is advisable for those older than 50 years to meet their RDA mainly by consuming foods fortified with B_{12} or a supplement containing B_{12}.

i. In view of evidence linking folate intake with neural tube defects in the fetus, it is recommended that all women capable of becoming pregnant consume 400 μg from supplements or fortified foods in addition to intake of food folate from a varied diet.

j. It is assumed that women will continue consuming 400 μg from supplements or fortified food until their pregnancy is confirmed and they enter prenatal care, which ordinarily occurs after the end of the periconceptional period—the critical time for formation of the neural tube.

NOTE: A Tolerable Upper Intake Level (UL) is the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population. Unless otherwise specified, the UL represents total intake from food, water, and supplements. Due to a lack of suitable data, ULs could not be established for vitamin K, thiamin, riboflavin, vitamin B_{12}, pantothenic acid, biotin, and carotenoids. In the absence of a UL, extra caution may be warranted in

consuming levels above recommended intakes. Members of the general population should be advised not to routinely exceed the UL. The UL is not meant to apply to individuals who are treated with the nutrient under medical supervision or to individuals with predisposing conditions that modify their sensitivity to the nutrient.

ND = Not determinable due to lack of data of adverse effects in this age group and concern with regard to lack of ability to handle excess amounts. Source of intake should be from food only to prevent high levels of intake.

Recommended Dietary Allowances (DRAs) for General Sales & Prescription only Borderline Products

Elements

Life Stage Group	**Levels**	**Calcium** (mg/d)	**Chromium** (µg/d)	**Copper** (µg /d)	**Fluoride** (mg/d)	**Iodine** (µg/d)	**Iron** (mg/d)	**Magnesium** (mg/d)	**Manganese** (mg/d)	**Molybdenum** (µg/d)	**Phosphorus** (mg/d)	**Selenium** (µg/d)	**Zinc** (mg/d)	**Potassium** (g/d)	**Sodium** (g/d)	**Chloride** (g/d)
2-8 years	Maximum	1,000	10	400	1	Not allowed	12	60	1.5	22	500	17	4	3.8	1.2	1.9
	Minimum	500	5	200	0.5	Not allowed	6	30	0.75	11	250	8.5	2	1.9	0.6	0.95
	Therapeutic Level	>1,000	>10	>400	>1	Not allowed	>12	>60	>1.5	>22	>500	>17	>4	>3.8	>1.2	>1.9
	Tolerable Upper Intake Level (UL)	2,500	ND	3,000	2.2	300	40	110	3	600	3.0g	150	12	ND	1.9	2.9
9-18 years	Maximum	1,000	25	700	3.2	Not allowed	22	220	1.9	34	800	26	7	4.5	1.5	2.3
	Minimum	500	12.5	350	1.6	Not allowed	11	110	0.95	17	400	13	3.5	2.25	0.75	1.15

	Therapeutic Level	>1,000	>25	>700	>3.2	Not allowed	>22	>220	>1.9	>34	>800	>26	>7	>4.5	>1.5	>2.3
	Tolerable Upper Intake Level (UL)	3,000	ND	8,000	10	900	45	350	9	1,700	4.0g	400	34	ND	2.3	3.6
Life Stage Group	**Levels**	**Calcium** (mg/d)	**Chromium** (µg/d)	**Copper** (µg /d)	**Fluoride** (mg/d)	**Iodine** (µg/d)	**Iron** (mg/d)	**Magnesium** (mg/d)	**Manganese** (mg/d)	**Molybdenum** (µg/d)	**Phosphorus** (mg/d)	**Selenium** (µg/d)	**Zinc** (mg/d)	**Potassium** (g/d)	**Sodium** (g/d)	**Chloride** (g/d)
>18 years (Adults)	Maximum	750	35	200	4	Not allowed	33	220	5	75	700	26	5	3.5	2.4	3.4
	Minimum	375	17.5	100	2	Not allowed	16.5	110	2.5	37.5	350	13	2.5	1.75	1.2	1.7
	Therapeutic Level	>750	>35	>200	>4	Not allowed	>33	>220	>5	>75	>700	>26	>5	>3.5	>2.4	>3.4
	Tolerable Upper Intake Level (UL)	2,500	ND	10,000	10	1,100	45	350	11	2,000	4.0g	400	40	ND	2.3	3.6
Pregnancy	Desirable level	750	35	200	4	Not allowed	33	220	5	75	700	28	7	3.5	2.4	3.4
	Tolerable Upper Intake Level (UL)	2,500	ND	10,000	10	1,100	45	350	11	2,000	3.5g	400	40	ND	40	2.3

Lactating woman	Desirable level	750	35	200	4	Not allowed	33	270	5	75	700	35	9	3.5	2.4	3.4
	Tolerable Upper Intake Level (UL)	2,500	ND	10,000	10	1,100	45	350	11	2,000	4.0g	400	40	ND	2.3	3.6

Recommended Dietary Allowances (DRAs) for Borderline Products

Vitamins & Elements

The levels of vitamins and elements have been determined using the RDA values. An RDA is the average daily dietary intake level sufficient to meet the nutrient requirements of nearly all (97–98 percent) healthy individuals in a group. It is calculated from an Estimated Average Requirement (EAR).

If sufficient scientific evidence is not available to establish an EAR, and thus calculate an RDA, an AI is usually developed. For healthy breast-fed infants, an AI is the mean intake. The AI for other life stage and gender groups is believed to cover the needs of all healthy individuals in the groups, but lack of data or uncertainty in the data prevent being able to specify with confidence the percentage of individuals covered by this intake.

100% RDA -Maximum level

50% RDA - Minimum level

>100% RDA -Therapeutic level

Categorization according to the RDA Value

1) >100% RDA- Therapeutic Borderline Product, Prescription only-Schedule IIB

2) 100%<RDA>50%- Pharmacy only- Schedule IIA

3) < 50% RDA These products no need to registered as Borderline Product

Tolerable Upper Intake Level (UL)

Tolerable Upper Intake Level (UL) - is the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population. Unless otherwise specified, the UL represents total intake from food, water, and supplements. In the absence of a UL, extra caution may be warranted in consuming levels above recommended intakes. Members of the general population should be advised not to routinely exceed the UL. The UL is

not meant to apply to individuals who are treated with the nutrient under medical supervision or to individuals with predisposing conditions that modify their sensitivity to the nutrient

Terms and conditions:

1. General Sales (Schedule I) borderline products and schedule IIA borderline products are not permitted for the age group below 2 years. Hence dosage regimens for < 2years will not be permitted on the label.

2. A Product containing a single active ingredient considered as a drug. This is valid only for vitamins and elements.

3. Glucosamin only & Glucosamin combination products will be registered as borderline products.

4. All injections will be registered under pharmaceuticals.