



DESCRIPTION

Ready-to-drink low Phenylalanine Medical Food

A blend of whey protein isolate (glycomacropeptide – GMP), essential and non-essential amino acids, carbohydrate, fat (including docosahexaenoic acid – DHA), vitamins and minerals.

USE UNDER MEDICAL SUPERVISION

INDICATIONS

For use in the dietary management of Phenylketonuria (PKU) for ages 1 year and over.



DOSAGE AND ADMINISTRATION

To be determined by the clinician or dietitian and is dependent on the age, body weight, and medical condition of the patient.

Each 180 mL (6 fl oz) bottle of PKU sphere NEXT15 provides 15 g of Protein Equivalent and contains 23 mg of phenylalanine.

PREPARATION GUIDELINES

Shake vigorously before use. If desired, refrigerate before use.

STORAGE

Store in a cool dry place or refrigerate before use if desired.

The product should be consumed immediately after opening. However, if this is not possible, seal cap and consume within 6 hours at room temperature or within 24 hours if refrigerated. Re-shake well before use.

IMPORTANT NOTICE

Must only be consumed by people with proven PKU under strict medical supervision.

Diet must be supplemented with natural protein, water, and other nutrients in prescribed quantities to supply phenylalanine, fluid, and general nutrition requirements.

Not for intravenous use.

For enteral use only (oral or tube feeding).

Not for use as a sole source of nutrition.

PACK SIZE	NET	HCPCS CODE	REIMBURSEMENT CODE
15 x 180 ml (6 fl oz) bottles	2.7 L (90 fl oz) (0.70 gal)	B4162 & B4157	12539-0026-00

PKU sphere NEXT Nutrition Information

	Units	per 100 mL	per 180 mL (1 bottle)
Calories / Calories	kcal	90	161
Protein Equivalent	g	8.4	15
L-Phenylalanine	mg	13	23
Total Carbohydrate	g	4.3	7.7
Sugars	g	3.9	7.0
Total Fat	g	4.3	7.7
Saturated Fat	g	0.8	1.4
Docosahexaenoic Acid	mg	47	85
VITAMINS			
Vitamin A	µg RE	100	180
Vitamin D	µg	3.8	6.8
Vitamin E	mg α TE	1.4	2.5
Vitamin C	mg	10	18
Vitamin K	µg	9	16
Thiamin	mg	0.23	0.41
Riboflavin	mg	0.29	0.52
Niacin	mg	1.3	2.3
Vitamin B6	mg	0.23	0.41
Folic Acid	µg	40	72
Vitamin B12	µg	0.6	1.1
Pantothenic acid	mg	0.8	1.4
Biotin	µg	7.6	13.7
Choline	mg	76	137
MINERALS			
Sodium	mg	125	225
Potassium	mg	108	194
Chloride	mg	2.3	4.1
Calcium	mg	249	448
Phosphorus	mg	154	277
Magnesium	mg	44	79
Iron	mg	2.9	5.2
Copper	mg	0.23	0.41
Zinc	mg	2.2	4
Manganese	µg	144	259
Iodine	µg	34	61
Molybdenum	µg	7.7	14
Selenium	µg	12	22
Chromium	mg	3.8	6.8
Taurine	mg	16	29
Carnitine	mg	7.9	14
AMINO ACIDS			
L-Alanine	g	0.35	0.63
L-Arginine	g	0.41	0.74
L-Aspartic Acid	g	0.57	1.03
L-Cystine	g	0.12	0.22
L-Glutamine	g	1.14	2.05
Glycine	g	0.30	0.54
L-Histidine	g	0.30	0.54
L-Isoleucine	g	0.60	1.08
L-Leucine	g	1.27	2.29
L-Lysine	g	0.49	0.88
L-Methionine	g	0.12	0.22
L-Phenylalanine	mg	13	23
L-Proline	g	0.68	1.22
L-Serine	g	0.43	0.77
L-Threonine	g	0.97	1.75
L-Tryptophan	g	0.17	0.31
L-Tyrosine	g	0.95	1.71
L-Valine	g	0.48	0.86

Ingredients: Water, Casein glycomacropeptide (milk), Sugar, Vegetable oils (High oleic sunflower oil, Canola oil). Contains 2% or less of: L-leucine, L-tyrosine, Calcium phosphate, Citric acid esters of mono- and diglycerides, Mono and diglycerides of fatty acids, Natural flavors, Magnesium acetate, L-arginine, L-histidine, Glycine, Choline bitartrate, L-tryptophan, Xanthan gum, L-cystine, *Schizochytrium sp.* oil*, Ascorbic acid, Potassium hydroxide, Zinc gluconate, Taurine, L-carnitine L-tartrate, Ferrous sulfate, L-methionine, Vitamin D3, DL-alpha tocopheryl acetate, Copper gluconate, Niacinamide, Retinyl Acetate, Manganese gluconate, Pantothenic acid, Sodium selenite, Vitamin K1, Biotin, Vitamin B12, Folic acid, Potassium iodide, Thiamine hydrochloride, Chromium chloride, Vitamin B6, Riboflavin, Sodium molybdate, Ascorbyl palmitate and Tocopherols (preservatives).

Contains: Milk.

*A source of docosahexaenoic acid (DHA).

Osmolality: 640 mOsm/kg

Manufactured in France for Vitaflo USA, LLC. 1007 US Highway 202/206, Building JR-2, Bridgewater, NJ 08807

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