



sphere¹⁵

DESCRIPTION

Powdered 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) from 3 years of age.



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 27 g packet of PKU sphere15 provides 15 g of protein equivalent and contains 23 mg of phenylalanine.

PREPARATION GUIDELINES

1. Measure 120 ml (4 fl oz) of cold water into a cup with a lid.
2. Add 1 packet of PKU sphere15.
3. Secure lid and shake until powder is fully dissolved.
4. PKU sphere15 is now ready to use.

The product should be freshly prepared and consumed immediately. However, if this is not possible, any prepared product must be tightly covered and consumed within 4 hours at room temperature or within 24 hours if refrigerated.

Re-shake 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.

Not for use as a sole source of nutrition.

STORAGE

Store in a cool dry place.

Packets are designed for single use and should be used immediately once opened. Any unused powder in a packet must be tightly sealed and used within 24 hours.

Ordering and Reimbursement Information

PKU Sphere15				
Flavor	Packaging	Net Weight	Reimbursement Code	HCPCS Code
Vanilla	30 x 27 g (0.95 oz) packets	810 g (28.5 oz) (1.78 lb)	12539-0021-43	B4162 & B4157
Red Berry			12539-0021-13	

PKU sphere15 Nutrition Information

	Units	per 100 g	per 27 g (1 packet)
Calories	kcal	340	90
Protein equivalent	g	56	15
Total carbohydrate	g	18	4.9
Sugars	g	7.0	1.9
Total fat	g	4.5	1.2
Saturated fat	g	1.0	0.3
Docosahexaenoic acid (DHA)	mg	314	85
VITAMINS			
Vitamin A	µg	690	186
Vitamin D	µg	12	3.2
Vitamin E	mg	14	3.8
Vitamin C	mg	80	22
Vitamin K	µg	59	16
Thiamin	mg	1.5	0.40
Riboflavin	mg	1.5	0.40
Niacin	mg	8.6	2.3
Vitamin B6	mg	1.4	0.38
Folate	µg DFE	260	70
Vitamin B12	µg	4.1	1.1
Pantothenate	mg	32	8.6
Biotin	µg	5.1	1.4
Choline	mg	510	138
MINERALS			
Sodium	mg	810	219
Potassium	mg	590	159
Chloride	mg	20	5.4
Calcium	mg	1010	273
Phosphorus	mg	1050	283
Magnesium	mg	290	78
Iron	mg	19	5.1
Copper	mg	1.5	0.40
Zinc	mg	19	5.1
Manganese	mg	1.0	0.27
Iodine	µg	210	57
Molybdenum	µg	51	14
Selenium	µg	76	20
Chromium	µg	30	8.1
AMINO ACIDS			
L-Alanine	g	2.36	0.64
L-Arginine	g	2.73	0.74
L-Aspartic acid	g	3.73	1.01
L-Cystine	g	0.69	0.19
L-Glutamine	g	7.72	2.08
Glycine	g	2.02	0.55
L-Histidine	g	2.01	0.54
L-Isoleucine	g	4.06	1.10
L-Leucine	g	8.62	2.33
L-Lysine	g	2.72	0.73
L-Methionine	g	0.80	0.22
L-Phenylalanine	mg	87	23
L-Proline	g	4.58	1.24
L-Serine	g	2.88	0.78
L-Threonine	g	6.55	1.77
L-Tryptophan	g	1.15	0.31
L-Tyrosine	g	6.43	1.74
L-Valine	g	3.27	0.88

Osmolality PKU sphere15 Vanilla: 27 g (1 packet) + 120 ml (4 fl oz) water = 572 mOsm/kg

Osmolality PKU sphere15 Red Berry: 27 g (1 packet) + 120 ml (4 fl oz) water = 609 mOsm/kg

VANILLA (artificially flavored)

Ingredients: Whey Protein Isolate (Milk), L-Leucine, Sugar, L-Tyrosine, Natural and Artificial Flavor, Modified Corn Starch, Soy Lecithin, L-Arginine, Calcium Lactate, Magnesium Phosphate, Calcium Phosphate, Dried Corn Syrup, L-Histidine, Choline Bitartrate, Glycine, Refined Tuna Oil (Fish), L-Tryptophan, L-Lysine L-Aspartate, L-Cystine, Sodium Ascorbate, Zinc Gluconate, Maltodextrin, Dipotassium Phosphate, Ferrous Sulfate, L-Methionine, Sucralose, DL-Alpha Tocopheryl Acetate, Potassium Iodide, Mono- and Diglycerides, Chromium Chloride, Sodium Selenite, Sodium Molybdate, Copper Gluconate, Niacinamide, Manganese Gluconate, Vitamin A Acetate, Calcium Pantothenate, Vitamin D3, Vitamin B12, Biotin, Folic Acid, Thiamine Hydrochloride, Pyridoxine Hydrochloride, Riboflavin, Vitamin K1, Tocopherols (Preservative).

Contains: Fish (Tuna), Milk and Soy.

RED BERRY (artificially flavored)

Ingredients: Whey Protein Isolate (Milk), L-Leucine, L-Tyrosine, Natural and Artificial Flavor, Modified Corn Starch, Sugar, Soy Lecithin, L-Arginine, Calcium Lactate, Magnesium Phosphate, Calcium Phosphate, Dried Corn Syrup, L-Histidine, Choline Bitartrate, Glycine, Refined Tuna Oil (Fish), L-Tryptophan, Beet Juice Concentrate (Color), L-Lysine L-Aspartate, L-Cystine, Sodium Ascorbate, Zinc Gluconate, Maltodextrin, Dipotassium Phosphate, Ferrous Sulfate, L-Methionine, Sucralose, DL-Alpha Tocopheryl Acetate, Potassium Iodide, Mono- and Diglycerides, Chromium Chloride, Sodium Selenite, Sodium Molybdate, Copper Gluconate, Niacinamide, Manganese Gluconate, Vitamin A Acetate, Calcium Pantothenate, Vitamin D3, Vitamin B12, Biotin, Folic Acid, Thiamine Hydrochloride, Pyridoxine Hydrochloride, Riboflavin, Vitamin K1, Tocopherols (Preservative).

Contains: Fish (Tuna), Milk and Soy.

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

Tel: 888-848-2356 | Fax: 631-693-2002 | Email: vitafloNAM@vitaflousa.com
VitafloUSA.com | Code: VFUSA_11221_100722

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