



sphere[®]₂₀

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 35 g packet of PKU sphere20 provides 20 g of protein equivalent and contains 30 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 sphere20.
3. Secure lid and shake until powder is fully dissolved.
4. PKU sphere20 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 Sphere20				
Flavor	Packaging	Net Weight	Reimbursement Code	HCPCS Code
Vanilla	30 x 35 g (1.23 oz) packets	1.05 kg (37 oz) (2.31 lb)	12539-0021-12	B4157 & B4162
Red Berry			12539-0021-11	
Chocolate			12539-0022-05	
Banana			12539-0025-82	
Lemon			12539-0025-80	

PKU sphere20 Nutrition Information

	Units	Vanilla/ Red Berry		Chocolate		Banana		Lemon	
		per 100 g	per 35 g (1 packet)	per 100 g	per 35 g (1 packet)	per 100 g	per 35 g (1 packet)	per 100 g	per 35 g (1 packet)
Calories	kcal	340	120	340	120	340	120	330	120
Protein equivalent	g	56	20	56	20	56	20	56	20
Total carbohydrate	g	18	6.3	18	6.3	19	6.7	17	6.0
Sugars	g	7.0	2.5	8.5	3.0	6.5	2.3	7.5	2.6
Total fat	g	4.5	1.6	4.5	1.6	4.5	1.6	4.5	1.6
Saturated fat	g	1.0	0.4	1.0	0.4	1.5	0.5	1.5	0.5
Docosahexaenoic acid (DHA)	mg	314	110	314	110	314	110	314	110
VITAMINS									
Vitamin A	µg RE	690	241	690	241	690	241	690	241
Vitamin D	µg	12	4.2	12	4.2	12	4.2	12	4.2
Vitamin E	mg α TE	14	4.9	14	4.9	14	4.9	14	4.9
Vitamin C	mg	80	28	80	28	80	28	80	28
Vitamin K	µg	59	21	59	21	59	21	59	21
Thiamin	mg	1.5	0.52	1.5	0.52	1.5	0.52	1.5	0.52
Riboflavin	mg	1.5	0.52	1.5	0.52	1.5	0.52	1.5	0.52
Niacin	mg	8.6	3.0	8.6	3.0	8.6	3.0	8.6	3.0
Vitamin B6	mg	1.4	0.49	1.4	0.49	1.4	0.49	1.4	0.49
Folic acid	µg	260	91	260	91	260	91	260	91
Vitamin B12	µg	4.1	1.4	4.1	1.4	4.1	1.4	4.1	1.4
Pantothenic acid	mg	5.1	1.8	5.1	1.8	5.1	1.8	5.1	1.8
Biotin	µg	32	11	32	11	32	11	32	11
Choline	mg	510	178	510	178	510	178	510	178
MINERALS									
Sodium	mg	810	283	810	283	810	283	810	283
Potassium	mg	590	206	590	206	590	206	590	206
Chloride	mg	20	7.0	20	7.0	20	7.0	20	7.0
Calcium	mg	1010	353	1010	353	1010	353	1010	353
Phosphorus	mg	1050	367	1050	367	1050	367	1050	367
Magnesium	mg	290	101	290	101	290	101	290	101
Iron	mg	19	6.6	19	6.6	19	6.6	19	6.6
Copper	mg	1.5	0.52	1.5	0.52	1.5	0.52	1.5	0.52
Zinc	mg	19	6.6	19	6.6	19	6.6	19	6.6
Manganese	mg	1.0	0.35	1.0	0.35	1.0	0.35	1.0	0.35
Iodine	µg	210	74	210	74	210	74	210	74
Molybdenum	µg	51	18	51	18	51	18	51	18
Selenium	µg	76	27	76	27	76	27	76	27
Chromium	µg	30	10	30	10	30	10	30	10
AMINO ACIDS									
L-Alanine	g	2.36	0.83	2.36	0.83	2.36	0.83	2.36	0.83
L-Arginine	g	2.73	0.96	2.73	0.96	2.73	0.96	2.73	0.96
L-Aspartic acid	g	3.73	1.31	3.73	1.31	3.73	1.31	3.73	1.31
L-Cystine	g	0.69	0.24	0.69	0.24	0.69	0.24	0.69	0.24
L-Glutamine	g	7.72	2.70	7.72	2.70	7.72	2.70	7.72	2.70
Glycine	g	2.02	0.71	2.02	0.71	2.02	0.71	2.02	0.71
L-Histidine	g	2.01	0.70	2.01	0.70	2.01	0.70	2.01	0.70
L-Isoleucine	g	4.06	1.42	4.06	1.42	4.06	1.42	4.06	1.42
L-Leucine	g	8.62	3.02	8.62	3.02	8.62	3.02	8.62	3.02
L-Lysine	g	2.72	0.95	2.72	0.95	2.72	0.95	2.72	0.95
L-Methionine	g	0.80	0.28	0.80	0.28	0.80	0.28	0.80	0.28
L-Phenylalanine	mg	87	30	87	30	87	30	87	30
L-Proline	g	4.58	1.60	4.58	1.60	4.58	1.60	4.58	1.60
L-Serine	g	2.88	1.01	2.88	1.01	2.88	1.01	2.88	1.01
L-Threonine	g	6.55	2.29	6.55	2.29	6.55	2.29	6.55	2.29
L-Tryptophan	g	1.15	0.40	1.15	0.40	1.15	0.40	1.15	0.40
L-Tyrosine	g	6.43	2.25	6.43	2.25	6.43	2.25	6.43	2.25
L-Valine	g	3.27	1.14	3.27	1.14	3.27	1.14	3.27	1.14

Average Osmolality PKU sphere20: 1 packet (35 g) + 120 ml (4 fl oz) = 800 mOsm/kg

Manufactured in the Netherlands for Vitaflo USA, LLC.
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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.

CHOCOLATE (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.

BANANA (artificially flavored)

Ingredients: Whey Protein Isolate (Milk), L-Leucine, Natural and Artificial Flavor, L-Tyrosine, Sugar, 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, Sucralose, Maltodextrin, Dipotassium Phosphate, Ferrous Sulfate, L-Methionine, 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, Tocopherols (Preservative), Thiamine Hydrochloride, Pyridoxine Hydrochloride, Riboflavin, Vitamin K1.

Contains: Fish (Tuna), Milk and Soy.

LEMON (artificially flavored)

Ingredients: Whey Protein Isolate (Milk), L-Leucine, L-Tyrosine, Natural and Artificial Flavor, Modified Corn Starch, Sugar, Soy Lecithin, L-Arginine, Citric Acid, 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, Sucralose, Maltodextrin, Dipotassium Phosphate, Ferrous Sulfate, L-Methionine, 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, Tocopherols (Preservative), Thiamine Hydrochloride, Pyridoxine Hydrochloride, Riboflavin, Vitamin K1.

Contains: Fish (Tuna), Milk and Soy.



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