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Product:	XPhe smart J neutral		GB
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1. Product description

Name : **XPhe smart J neutral**

Extended name: XPhe smart J neutral

Food for special medical purposes- with sweetener. Phenylalanine-free protein supplement for the dietary management of Phenylketonuria (PKU) or Hyperphenylalaninemia (HPA). Suitable from 9 to 14 years of age.

Sales denomination: Food for special medical purposes

2. Specific requirements according to food law

The product is intended as a dietary food for special medical purposes according to Regulation (EC) No 609/2013.

The product complies with the relevant German, as well as European, provisions of the food law, especially the provisions of the Food, Consumer Goods and Feed Code (LFGB) and Regulation (EC) No 178/2002.

The product is produced in a factory that has a certified quality system (ISO 9001-2015).

The raw materials for the product correspond to the purity requirements obtainable according to the generally recognized rules of technology and are fully suitable for human consumption.

Packaging which can directly or indirectly influence the quality of the food must be suitable for use in foodstuffs. Packaging and transport containers are designed to protect the product against external influences. The packing materials and transport containers in contact with the raw material must not impair the quality of the raw material. The packaging materials used comply with the legal requirements of Regulation (EC) No 1935/2004 and Regulation (EC) No 10/2011 on materials and articles (made of plastic) intended to come into contact with foodstuffs. There is no odor, taste or other impairment of the delivered goods from the packaging material.

3. Product properties

3.1. Ingredients

Date: 12.04.2021

L-lysine-L-aspartate, glycine, L-leucine, L-tyrosine, L-glutamine, L-arginine-L-aspartate, L-threonine, L-proline, L-serine, L-valine, calcium phosphate, L-isoleucine, L-alanine, magnesium L-aspartate, L-histidine, thickener: distarch phosphate, maltodextrin, L-cystine, N-acetyl-L-methionine, L-tryptophan, emulsifier: sunflower lecithin, acid: citric acid, sweetener: sucralose, stabilizer: guar gum, calcium carbonate, magnesium carbonate, choline, inositol, ferrous sulphate, taurine, vitamin C, zinc sulphate, L-carnitine, niacin, vitamin E, manganese sulphate, pantothenic acid, cupric sulphate, vitamin B6, vitamin B2, vitamin B1, sodium fluoride, vitamin A, chromium (III) chloride, folic acid, potassium iodide, biotin, sodium molybdate, sodium selenite, vitamin K, vitamin D, vitamin B12.

created, checked & released	18.08.2021
Angélique Gebbing	

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3. 2. Nutrition information

		100 g	14,5 g	
Energy	kJ	1310	190	
	kcal	309	45	
Fat	g	<0,3	<0,04	
of which saturates	g	<0,1	<0,02	
Carbohydrate	g	5	0,7	
of which sugars	g	0,04	0,01	
Fiber	g	1,2	0,17	
Protein eqv.	g	70	10	
Salt	g	0	0	
		100 g	14,5 g	per g protein
Vitamins				
Vitamin A	µg	1260	183	18
Vitamin D	µg	28	4	0,4
Vitamin E	mg	25	3,6	0,35
Vitamin K1	µg	90	13	1,3
Vitamin C	mg	147	21	2
Thiamin (Vit. B1)	mg	2,4	0,36	0,035
Riboflavin (Vit. B2)	mg	3	0,4	0,04
Niacin	mg	56	8	0,8
Vitamin B6	mg	2,3	0,3	0,03
Folic acid	µg	280	41	4
Vitamin B12	µg	5	0,7	0,065
Biotin	µg	56	8	0,8
Pantothenic acid	mg	9	1,3	0,13
Minerals				
Calcium	mg	1960	284	28
Phosphorus	mg	931	135	13
Magnesium	mg	378	55	5
Trace elements				
Iron	mg	25	4	0,36
Zinc	mg	25	4	0,36
Copper	mg	3	0,4	0,04
Manganese	mg	8	1,1	0,11
Fluoride	mg	1	0,15	0,015
Selenium	µg	102	15	1,5
Chromium	µg	140	20	2
Molybdenum	µg	119	17	1,7
Iodine	µg	315	46	4,5

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FURTHER NUTRITION INFORMATION				
L-Carnitine	mg	63	9	0,9
Choline	mg	630	91	9
myo-Inositol	mg	329	48	5
Taurine	mg	70	10	1
Amino acids	g	84	12	1,2
L-Alanine	g	3,8	0,55	0,05
L-Arginine	g	3,4	0,50	0,05
L-Aspartic acid	g	10,1	1,46	0,14
L-Cystine	g	2,0	0,29	0,03
L-Glutamine	g	6,4	0,93	0,09
Glycine	g	8,1	1,17	0,12
L-Histidine	g	3,1	0,45	0,04
L-Isoleucine	g	4,4	0,64	0,06
L-Leucine	g	7,6	1,11	0,11
L-Lysine	g	4,9	0,71	0,07
L-Methionine	g	1,5	0,21	0,02
L-Phenylalanine	g	-	-	-
L-Proline	g	5,4	0,78	0,08
L-Serine	g	4,8	0,69	0,07
L-Threonine	g	5,4	0,78	0,08
L-Tryptophan	g	1,5	0,21	0,02
L-Tyrosine	g	6,7	0,97	0,10
L-Valine	g	4,8	0,69	0,07

4. Quality parameters and reference values

4.1. Sensoric properties

appearance: white powder

consistency: fine powder

odour: typical, almost neutral

taste: typical, almost neutral

4.2. Potential allergens

Potential allergen	present (Y/N)	Cross-contamination possible (Y/N)
Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut, or hybrid strains thereof) and products thereof.	N	N
Crustaceans and products thereof	N	N
Eggs and products thereof	N	N
Fish and products thereof	N	N
Peanuts and products thereof	N	N
Soybeans and products thereof	N	N
Milk and products thereof (including lactose)	N	N
Nuts (i.e. almond, hazelnut, walnut, cashew nut, pecan, Brazil nut, Pistachio nut, Macadamia nut and Queensland nut.) and products thereof	N	N
Celery and products thereof	N	N
Mustard and products thereof	N	N
Sesame seeds and products thereof	N	N
Sulphur dioxide at concentration > 10mg/kg (SO ₂)	N	N
Lupin and products thereof	N	N
Molluscs and products thereof	N	N

4.3. Statement on GMO

Neither genetically modified raw materials, nor genetic engineering methods are used in the production of the above-mentioned product. The product is therefore not subject to the requirements of Regulation (EC) No 1829/2003 on genetically modified food and feed and is not subject to labeling requirements in accordance with Regulation (EC) No 1830/2003 on the traceability and labeling of genetically modified organisms.

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4.4. Microbiological requirements

Parameter	Guide value	Warning value	Method
TAMC/g	5×10^3	5×10^4	§ 64 LFGB L 00.00-88-1 (ISO 4833-1:2013)
Enterobacteriaceae/ g	1×10^1	1×10^2	§ 64 LFGB L 00.00-133/2 (ISO 21528-2)
E. coli/ 1 g	-	n.d.	DIN EN ISO 16649-3
coagulase positive Staphylococci / 1g	1×10^1	1×10^2	§ 64 LFGB L 00.00-56 (ISO 6888-2)
presumptive B. cereus / g	5×10^1	5×10^2	BAV-IM-5.4-12-01 (validiert gg. ISO 7932)
Moulds / g	1×10^2	1×10^3	ISO 21527-2
Listeria monocytogenes/ 25 g	-	n.d.	BAV-IM-5.4-70 (validiert gg. ISO 11290-1)
Salmonella/ 25 g	-	n.d.	BAV-IM-5.4-09-01:2016 (validiert gg. ISO 6579)

4.5. Chemical and physical properties

	Average values	Solution
pH-value	6,0-6,3	29 g / 150 ml water
Humidity	< 3 %	powder
Osmolality	1180-1200 mosmol/kg	29 g / 150 ml water
Bulk density	0,50-0,55 g/cm ³	powder

5. Form of delivery

Packaging:

Folding box -290 g

Tin- 500 g

6. Shelf life

24 months after production date

7. Storage

Cool and dry

8. Traceability

The traceability is guaranteed by the best before date and by the batch number.