Am Strassbach 5
D - 61169 Friedberg
Fon ++49 (0) 60 31 - 1667220
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Vertriebszentrum Burgheim
Kreuterstr. 14
D – 86666 Burgheim / Strass
Fon ++49 (0) 84 32 - 94860
Fax ++49 (0) 84 32 - 948619

Bankverbindung :
Volksbank Mittelhessen eG
Kto. 87 860 701 BLZ 513 900 00

HRB 2023 - Amtsgericht Friedberg
Sitz der Gesellschaft Friedberg
Geschäftsführer Dr. Bernhard Hoffmann
Volker Sieg

CONFIDENTIAL
ONLY FOR PRESENTATION AT THE COMPETENT AUTHORITY

19.09.2025

CERTIFICATE OF QUALITY

XPhe Infant Mix^{LCP}

We herewith confirm that the product "XPhe Infant Mix^{LCP}" is produced in a company which has established a Quality Management System (ISO 9001-2015) certified by TÜV Süd.
The ISO-certification ensures safety to metaX in giving guarantee for a consistently high quality. Workflow and quality checks are regulated in a manual.

metaX Institut für Diätetik GmbH

Angélique Gebbing
Director Regulatory Affairs
State certified food chemist

Analysenzertifikat / *Certificate of Analysis*

1. Produktdaten/*product data*	
Produkt/*product*	**XPhe Infant**
Charge/*batch*	**INF/5192 (B)**
Mindesthaltbarkeitsdatum/*best before*	**11.01.2027**
Herstelldatum/*date of manufacture*	**15.07.2025**

2. Verpackung/ *packaging*	**interne Spezifikation/** *internal specification*		**korrekter Einsatz/** *correct usage*	
	Bezeichnung/*name*	**Art.-Nr.**	**Ja/***Yes*	**Nein/***No*
Packstoff/*packing material*	Weißblechdose 99/149	49-008-80200	X	
Umverpackung/*overpack*	-	-	-	
Messlöffel/*measuring spoon*	Nr. 310882 PP blau	49-008-50016	X	
Füllmenge/*filling quantity*	500 g		X	
Schutzgas/*protective gas*	Ja/Yes		X	

3. physikalische Parameter/ *physical properties*	**Einheit/***unit*	**Ist/***actual value*	**Soll/***nominal value*
Restfeuchte/*residual moisture*	%	1,8	< 3
Schüttdichte/*powder density*	g/100ml	35,2	31,0 – 37,0
Messlöffel/*measuring spoon*	g	3,5	3,4 – 3,6
pH Wert/*pH value*	-	7,01	6,7 – 7,8
Viskosität/*viscosity*	mPa*s	-	k. A.
Osmolalität/*osmolality*	mOsmol /kg	363	340 - 400
Sensorik/*sensory analysis* (Degustationsprotokoll QS FB)	Note:	1,0	< 4

	entspricht interner Spezifikation/ *complies with internal specification*	
	Ja/*Yes*	**Nein/***No*
Siebanalyse/*sieve analysis*	-	

4. biologische Parameter/ *biological properties*	**entspricht interner Spezifikation/** *complies with internal specification*		**Labor/** *laboratory*	**Befundnr./** *resultnr.*
	Ja/*Yes*	**Nein/***No*		
mikrobiologische Analyse/ *microbiological analysis*	X		BAV	25714610/1070412 25714609/1070412 25714611-20/1070425 25714621-25/1070430

5. chemische Parameter/ *chemical properties*	**entspricht interner Spezifikation/** *complies with internal specification*		**Labor/** *laboratory*	**Befundnr./** *resultnr.*
	Ja/*Yes*	**Nein/***No*		
Aminosäurenspektrum/ *amino acid analysis*	X		Intern	-
Mineralstoff- und Spurenelementanalytik/ *mineral and trace elements analysis*	-			
Fett- Kohlenhydrat- und Eiweißanalytik/ *fat, carbohydrate and protein analysis*	-			

6. Freigabe/*approval*	
Datum/*Date*	Unterschrift/*signature*
03.09.2025	

**BUNDESAMT FÜR VERBRAUCHERSCHUTZ
UND LEBENSMITTELSICHERHEIT**

Geschäftszeichen (bei Antwort bitte angeben)
111-xxxx-2-78(2003)

☎ 0228/6198 - 241
E-Mail: Sylvia.Musch@bvl.bund.de

Datum: 09. Juli 2003

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
▪ Dienststelle Bonn
Postfach 140162, 53056 Bonn

metaX Institut für Diätetik GmbH
Dieselstraße 23

61191 Rosbach

Anzeige von diätetischen Lebensmitteln nach § 4a Diätverordnung (bilanzierte Diäten)
Produkt "XPhe Infant Mix"

Anlagen: 0

Sehr geehrte Damen und Herren,

hiermit bestätige ich den Eingang Ihrer Anzeige nach § 4a Diätverordnung vom 21. Juni 2003 für das Produkt "XPhe Infant Mix".

Ich weise Sie darauf hin, dass diese Anzeige keine Prüfung des Produktes beinhaltet und den Hersteller nicht freistellt von der selbstverantwortlichen Einhaltung der lebensmittelrechtlichen Vorschriften.

Bei Änderung des Produktes (z. B. Produktname, Zusammensetzung usw.) ist eine Änderungsanzeige erforderlich. Ich bitte auch um Mitteilung, falls Sie das o. g. Produkt vom Markt nehmen sollten (mit Angabe des Datums).

Dieses Anzeigeverfahren ist kostenpflichtig. Der Kostenbescheid wird Ihnen gesondert zugestellt.

Mit freundlichen Grüßen

Im Auftrag

Dr. Sylvia Musch

IMPORTANT NOTICE Must only be used under medical supervision. Not for use as a sole source of nutrition. For enteral use only. Only for infants with proven Phenylketonuria (PKU) or Hyperphenylalaninemia (HPA).

DEFINITION AND INDICATION XPhe Infant Mix^{LCP} is a Phenylalanine-free infant formula for use in the dietary management of Phenylketonuria (PKU) or Hyperphenylalaninemia (HPA) in infants. **XPhe Infant Mix^{LCP}** consists of amino acids, fat and carbohydrate and is enriched with vitamins, minerals and trace elements. Like breast milk **XPhe Infant Mix^{LCP}** contains lactose as main carbohydrate and is enriched with LCPUFA-lipids.

DOSAGE The correct dosage is determined by the physician and/or dietitian and should be re-examined and adjusted in accordance with the results of regular monitoring. The dosage depends on age, body weight, protein requirements and the infant's individual Phenylalanine tolerance. The daily amount is determined individually and is given to the infant in combination with calculated amounts of breast milk and/or regular infant formula and/or low protein weaning food (beikost).

DIRECTIONS FOR USE The daily dosage of **XPhe Infant Mix^{LCP}** and other food (e. g. breast milk, infant formula or Beikost) is determined in a diet plan. The total daily amount of **XPhe Infant Mix^{LCP}** should be given as a bottle feed or a pap, divided into 3 – 5 single portions, evenly distributed during the day.
When prepared with drinking water only, **XPhe Infant Mix^{LCP}** gives a Phenylalanine (Phe) free bottle feed or pap, which can be used for lowering the blood Phe level. For preparing a Phe-reduced pap, **XPhe Infant Mix^{LCP}** is mixed with calculated amounts of starch, low protein biscuits and/or fruits.

XPhe Infant Mix^{LCP} must not be given without other protein containing foods (e. g. breast milk or regular infant formula) over a longer period of time. Medical supervision is indispensable in any case.

PREPARATION OF A BOTTLE FEED


Clean and boil bottle and teat before use.


Boil water and leave to cool down to approx. 40 °C.

Pour water into the bottle.


Loosen the powder with the scoop.


Take powder up loosely with the scoop.


Strip off powder with the back of a knife.


Determine the tara weight of the bottle. Carefully empty the scoop into the bottle. Weigh out and thus verify the amount of powder.


Put the lid safely on the bottle and shake.


Open bottle and fix the teat. Check drinking temperature (cheek test).

Always prepare bottle feed or pap freshly. Do not reuse any rest.

4 250174 111002

ADVICE FOR DENTAL HEALTH Carbohydrates are indispensable for the nutrition of a child. Like breast milk **XPhe Infant Mix^{LCP}** contains carbohydrate. Incorrect use of the bottle (frequent or continuous sucking) however can result in tooth decay (caries) and related damages to tooth health. Thus a bottle feed should only last for the time required for the food intake.

metaX Institut fuer Diaetetik GmbH · Am Strassbach 5 · 61169 Friedberg/Germany
+ 49 (0) 84 32 - 94 86 0 · service@metax.org · metax-shop.org · metax.org
008000 - 9963829 (freecall from A, D, NL)

21/06/22 d14,03/30

XPhe Mix^{LCP} Infant

Special Infant Formula
for Phenylketonuria (PKU) or Hyperphenylalaninemia (HPA)
FOOD FOR SPECIAL MEDICAL PURPOSES

Food for Special Medical Purposes. Phenylalanine-free infant formula for use in the dietary management of Phenylketonuria (PKU) or Hyperphenylalaninemia (HPA). Suitable for infants from birth onwards.

NUTRITION DECLARATION XPhe Infant Mix^{LCP}		100 g powder	100 ml ready-to-use**
Energy	kJ	2124	319
	kcal	508	76
Fat	g	28	4
of which			
saturates	g	5	0,8
mono-unsaturates	g	11	1,6
polyunsaturates	g	12	1,7
DHA	mg	112	17
Carbohydrate	g	54	8
of which sugars	g	25	4
lactose	g	24	3,5
maltodextrin	g	22	3
starch	g	8	1,2
Protein eqv.*	g	11	1,7
Salt	g	0,6	0,1
Vitamins			
Vitamin A	µg	570	86
Vitamin D3	µg	7	1
Vitamin E	mg	5	0,7
Vitamin K1	µg	24	3,6
Vitamin C	mg	58	9
Thiamin (Vit. B1)	mg	0,5	0,07
Riboflavin (Vit. B2)	mg	0,5	0,08
Niacin	mg	6	0,9
Vitamin B6	mg	0,5	0,08
Folic acid	µg	51	8
Vitamin B12	µg	1,3	0,2
Biotin	µg	14	2
Pantothenic acid	mg	4	0,6
Minerals			
Sodium	mg	260	39
Potassium	mg	500	75
Chloride	mg	380	57
Calcium	mg	500	75
Phosphorus	mg	335	50
Magnesium	mg	52	8
Trace elements			
Iron	mg	6	1
Zinc	mg	5	0,8
Copper	mg	0,36	0,05
Manganese	mg	0,4	0,06
Fluoride	mg	0,13	0,02
Selenium	µg	13	2
Chromium	µg	26	4
Molybdenum	µg	26	4
Iodine	µg	46	7
FURTHER NUTRITION INFORMATION			
L-Carnitine	mg	11	1,6
Choline	mg	77	12
Myo-Inositol	mg	51	8
Taurine	mg	39	6

Packed under protective atmosphere.
BEST BEFORE
see bottom stamp.

		100 g powder	100 ml ready-to-use**
Amino acids	g	13	2
(*1 g protein = 1,2 g amino acids)			
L-Alanine	g	0,5	0,08
L-Arginine	g	0,5	0,08
L-Aspartic acid	g	1,1	0,17
L-Cystine	g	0,3	0,05
L-Glutamic acid	g	1,8	0,27
Glycine	g	0,4	0,06
L-Histidine	g	0,4	0,06
L-Isoleucine	g	0,8	0,12
L-Leucine	g	1,3	0,20
L-Lysine	g	0,9	0,14
L-Methionine	g	0,2	0,03
L-Phenylalanine	g	–	–
L-Proline	g	1,1	0,17
L-Serine	g	0,7	0,11
L-Threonine	g	0,6	0,09
L-Tryptophan	g	0,3	0,05
L-Tyrosine	g	1,2	0,18
L-Valine	g	0,8	0,12

This tin contains approx. 33 servings at 15 g.

****Standard dilution**
15 g **XPhe Infant Mix^{LCP}** + 90 ml drinking water = 100 ml ready-to-use formula.
The enclosed scoop measures approx. 3,7 g **XPhe Infant Mix^{LCP}** when levelled.
Osmolality: 350 - 360 mosmol/kg drinking water.

INGREDIENTS Vegetable oils (rape seed oil, corn oil, palm oil, sunflower oil), ***lactose***, maltodextrin, modified starch, L-lysine-L-glutamate, calcium phosphate, L-leucine, potassium-L-glutamate, L-tyrosine, L-proline, L-arginine-L-aspartate, L-valine, L-isoleucine, L-serine, sodium chloride, magnesium-L-aspartate, L-threonine, L-alanine, L-histidine, glycine, L-tryptophan, L-cystine, L-aspartic acid, L-methionine, emulsifiers: E 472c & ***soy lecithin***, potassium citrate, potassium carbonate, ***docosahexaenoic acid (DHA)-rich fishoil*** (contains ***milk components***), choline, inositol, vitamin C, taurine, vanillin, ferrous sulphate, zinc sulphate, niacin, L-carnitine, vitamin E, pantothenic acid, manganese sulphate, cupric sulphate, vitamin A, vitamin B2, vitamin B6, vitamin B1, sodium fluoride, chromium(III)chloride, sodium molybdate, potassium iodide, folic acid, sodium selenite, vitamin K, biotin, vitamin D, vitamin B12.

STORAGE Store in a cool, dry place. Tin should be sealed properly after use. Once opened content should be used up within 4 weeks.

500 g e

Product Information
– for professionals only –

XPhe Infant Mix^{LCP}

In Short

- XPhe Infant Mix^{LCP} is a Food for Special Medical Purposes (FSMP) for use in the dietary management of Phenylketonuria (PKU) or Hyperphenylalaninemia (HPA)
- for infants, from birth onwards
- protein supplement free of Phenylalanine – in powder form
- with carbohydrate (mainly lactose) and fat
- like human breast milk enriched with LCP-fatty acids
- highly purified L-amino acids
- micronutrients in adequate amounts
- in 500 g tin

Product Profile

XPhe Infant Mix^{LCP} is a powdered mixture of highly purified L-amino acids free of Phenylalanine – especially for infants, from birth onwards.
XPhe Infant Mix^{LCP} contains carbohydrate and fat: Like breast milk XPhe Infant Mix^{LCP} contains lactose as main carbohydrate and is enriched with LCPUFA-lipids.
XPhe Infant Mix^{LCP} is enriched with vitamins, minerals and trace elements in adequate amounts.

Administration

The daily amount is determined individually and is given to the infant in combination with calculated amounts of breast milk and/or regular infant formula and/or low protein weaning food (beikost).

Preparation and Feeding

When prepared with drinking water only, XPhe Infant Mix^{LCP} gives a Phenylalanine (Phe) free bottle feed or pap, which can be used for lowering the blood Phe level. For preparing a Phe-reduced pap, XPhe Infant Mix^{LCP} is mixed with calculated amounts of starch, low protein biscuits and/or fruits.
Recipes for low-Phe paps are available in our booklets "PKU im ersten Lebensjahr"(PKU in the first year of life) and "Vom Säugling zum Löffeling" (From infant bottle to weaning food) – both in German language. These can be ordered from us free of charge.
XPhe Infant Mix^{LCP} must not be given without other protein containing foods (e.g. breast milk or regular infant formula) over a longer period of time. Medical supervision is indispensable in any case.

Advice for Dental Health Carbohydrates are indispensable for the nutrition of a child. Like breast milk XPhe Infant Mix^{LCP} contains carbohydrate. Incorrect use of the bottle (frequent or continuous sucking) however can result in tooth decay (caries) and related damages to tooth health. Thus a bottle feed should only last for the time required for the food intake. Please advise the parents accordingly.

Function XPhe Infant Mix^{LCP} substitutes that part of the protein in the diet which may not be taken up from natural food sources.

Indication XPhe Infant Mix^{LCP} is a food for special medical purposes and as a protein supplement suitable for the dietary management of Phenylketonuria (PKU) or Hyperphenylalaninemia (HPA).

Dosage The correct dosage of XPhe Infant Mix^{LCP} is determined by the physician and should be adjusted regularly in accordance with the results of periodical monitoring. The dosage depends on age, body weight, protein requirements and the infant's individual Phenylalanine tolerance. The daily dosage of XPhe Infant Mix^{LCP} and other food (e. g. breast milk, infant formula or Beikost) is determined in a diet plan. The total daily amount of XPhe Infant Mix^{LCP} should be given as a bottle feed or a pap, divided into 3 – 5 single portions, evenly distributed during the day.
The PKU-diet must be supplemented with energy, natural protein, other nutrients and water in prescribed quantities.

Important Notice Must only be used under medical supervision. Not for use as a sole source of nutrition. For enteral use only. Only for infants with proven with Phenylketonuria (PKU) or Hyperphenylalaninemia (HPA). Follow the instructions for use.

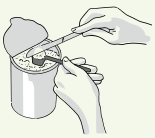
Preparation of a Bottle Feed


Clean and boil bottle and teat before use.

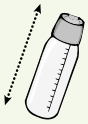

Boil water and leave to cool down to approx. 40 °C.
Pour water into the bottle.


Loosen the powder with the scoop.


Take powder up loosely with the scoop.


Strip off powder with the back of a knife.


Determine the tara weight of the bottle. Carefully empty the scoop into the bottle. Weigh out and thus verify the amount of powder.


Put the lid safely on the bottle and shake.


Open bottle and fix the teat. Check drinking temperature (cheek test).

Always prepare bottle feed or pap freshly. Do not reuse any rest.

NUTRITION INFORMATION

XPhe Infant Mix[LCP]		100 g powder	100 ml ready-to-use 15%**
Energy	kJ	2124	319
	kcal	508	76
Fat	g	28	4
of which			
saturates	g	5	0,8
mono-unsaturates	g	11	1,6
polyunsaturates	g	12	1,7
DHA	mg	112	17
Carbohydrate	g	54	8
of which sugars	g	25	4
Lactose	g	24	3,5
Maltodextrine	g	22	3
Starch	g	8	1,2
Protein eqv.*	g	11	1,7
Salt	g	0,6	0,1
Vitamins			
Vitamin A	µg	570	86
Vitamin D3	µg	7	1
Vitamin E	mg	5	0,7
Vitamin K1	µg	24	3,6
Vitamin C	mg	58	9
Thiamin (Vit. B1)	mg	0,5	0,07
Riboflavin (Vit. B2)	mg	0,5	0,08
Niacin	mg	6	0,9
Vitamin B6	mg	0,5	0,08
Folic acid	µg	51	8
Vitamin B12	µg	1,3	0,2
Biotin	µg	14	2
Pantothenic acid	mg	4	0,6
Minerals			
Sodium	mg	260	39
Potassium	mg	500	75
Chlorid	mg	380	57
Calcium	mg	500	75
Phosphor	mg	335	50
Magnesium	mg	52	8
Trace elements			
Iron	mg	6	1
Zinc	mg	5	0,8
Copper	mg	0,36	0,05
Manganese	mg	0,4	0,06
Fluoride	mg	0,13	0,02
Selenium	µg	13	2
Chromium	µg	26	4
Molybdenum	µg	26	4
Iodine	µg	46	7

FURTHER NUTRITION INFORMATION

XPhe Infant Mix[LCP]		100 g powder	100 ml ready-to-use 15%**
L-Carnitine	mg	11	1,6
Choline	mg	77	12
Myo-Inositole	mg	51	8
Taurine	mg	39	6
Amino acids	g	13	2
(*1 g protein = 1,2 g amino acids)			
L-Alanine	g	0,5	0,08
L-Arginine	g	0,5	0,08
L-Aspartic acid	g	1,1	0,17
L-Cystine	g	0,3	0,05
L-Glutamic acid	g	1,8	0,27
Glycine	g	0,4	0,06
L-Histidine	g	0,4	0,06
L-Isoleucine	g	0,8	0,12
L-Leucine	g	1,3	0,20
L-Lysine	g	0,9	0,14
L-Methionine	g	0,2	0,03
L-Phenylalanine	g	–	–
L-Proline	g	1,1	0,17
L-Serine	g	0,7	0,11
L-Threonine	g	0,6	0,09
L-Tryptophan	g	0,3	0,05
L-Tyrosine	g	1,2	0,18
L-Valine	g	0,8	0,12

**Standard dilution
15 g XPhe Infant Mix[LCP] + 90 ml drinking water
= 100 ml ready-to-use formula
The spoon enclosed in the tin contains approx. 3,7 g XPhe Infant Mix[LCP]. At best always weigh out the amount needed for the preparation of the bottle feed with XPhe Infant Mix[LCP].
Osmolality of standard solution
350 – 360 mosmol/kg

INGREDIENTS

Vegetable oils (rape seed oil, corn oil, palm oil, sunflower oil), ***lactose***, maltodextrin, modified starch, L-lysine-L-glutamate, calcium phosphate, L-leucine, potassium-L-glutamate, L-tyrosine, L-proline, L-arginine-L-aspartate, L-valine, L-isoleucine, L-serine, sodium chloride, magnesium L-aspartate, L-threonine, L-alanine, L-histidine, glycine, L-tryptophan, L-cystine, L-aspartic acid, L-methionine, emulsifiers: E 472c & ***soy lecithin***, potassium citrate, potassium carbonate, ***docosahexaenoic acid (DHA)-rich fishoil*** (contains ***milk components***), choline, inositol, vitamin C, taurine, vanillin, ferrous sulphate, zinc sulphate, niacin, L-carnitine, vitamin E, pantothenic acid, manganese sulphate, cupric sulphate, vitamin A, vitamin B2, vitamin B6, vitamin B1, sodium fluoride, chromium (III) chloride, sodium molybdate, potassium iodide, folic acid, sodium selenite, vitamin K, biotin, vitamin D, vitamin B12.

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phone +49 (0) 8432 - 94 86 0
e-mail service@metax.org
web metax-shop.org · metax.org

25/09/02 d14/03/30

Fat

- XPhe Infant Mix[LCP] contains vegetable oils (rapeseed-, corn-, sunflower- and palm-oil)
- following the example of mother's milk XPhe Infant Mix[LCP] is enriched with long chain polyunsaturated fatty acids (LC-PUFAs)
- the LC-PUFA source is a docosahexaenoic acid (DHA)-rich fish oil

Fat composition

XPhe Infant Mix[LCP] contains per		100 ml ready-to-use
Fat		4 g
of which	saturates	0,8 g
	mono-unsaturates	1,6 g
	polyunsaturatest	1,7 g
ratio of fatty acids ω-6 : ω-3 = 4 : 1		
Linoleic acid : α-Linolenic acid ratio = 5 : 1		

Fatty acids profile			% per 100 kcal	% of total fat
Butyric acid	4 : 0	–	–	–
Hexanoic acid	6 : 0	–	–	–
Caprylic acid	8 : 0	–	–	–
Capric acid	10 : 0	–	–	–
Lauric acid	12 : 0	–	0,003	0,06
Myristic acid	14 : 0	0,01 g	0,014	0,25
Myristoleic acid	14 : 1	–	–	–
Palmitic acid	16 : 0	0,59 g	0,8	14
Palmitoleic acid	16 : 1	0,01 g	0,018	0,3
Stearic acid	18 : 0	0,11 g	0,14	2,6
Oleic acid	18 : 1	1,56 g	2	38
Linoleic acid	18 : 2 n-6	1,41 g	2	34
α-Linolenic acid	18 : 3 n-3	0,30 g	0,4	7
Arachidic acid	20 : 0	0,07 g	0,1	1,8
Arachidonic acid	20 : 4 n-6	–	–	–
Eicosapentaenoic acid	20 : 5 n-3	0,003 g	0,004	0,07
Behenic acid	22 : 0	0,02 g	0,03	0,5
Docosahexaenoic acid	22 : 6 n-3	0,02 g	0,026	0,5

Delivery Unit	tin 6 x 500 g = 3000 g
Article Number	xx-001-20000
Delivery to	Pharmacies, clinics
Storage	Store in a cool, dry place.

metaX Institut fuer Diaetetik GmbH
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61169 Friedberg/Germany

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25/09/02 d14/03/30