

PRODUCT INFORMATION FILE VER. 07 del 11/2023
PKU EASY MICROTABS – GALEN PHARMA

REVISION HISTORY

Rev.	Data	Description	Editor
05	09/2023	Coating agent list update	S. Matricardi
06	11/2023	Added information on average amount of active ingredient per portion (14g)	S. Matricardi
07	11/2023	Added information about protein calculated as N*6.25	S. Matricardi

Legal category, in particular, according to Reg. (EC) No. 1333/2008 and amendments (Reg. (EU) No. 1129/2011):
13.2 Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)

Legal category (EU): Dietary foods for special medical purposes with amino acids

Indication and destination of use

A phenylalanine free foods indicated for use in the dietary management of Phenylketonuria in people from 3 years old and older.

Ingredient list: L-lysine-L-aspartate, L-leucine, L-tyrosine, glycine, stabilizer: sodium alginate, hydroxypropyl methylcellulose; L-arginine-L-aspartate, L-valine, L- glutamine, L-proline, L-isoleucine, L-threonine, anticaking agent: magnesium salt of fatty acids; L-serine, coating agent: hydroxypropyl-methylcellulose, isomalt, calcium carbonate, medium chain triglycerides; L-histidine, L-alanine, L-cystine, L-tryptophan, L-methionine, L-arginine, L-carnitine L-tartrate, L-taurine, dye: iron oxide and hydroxide.

Direction of use: the daily dose must be determined by the clinician or dietitian depending on the age, body weight and clinical condition of the patient. Use the measuring cup included in the box to dose the product. Indicatively we recommend to take 14g of microtabs per day, one measuring cup filled up to 20ml with microtabs (corresponding to 10g ca. of equivalent proteins), with water or other permitted liquid (including custard, jam or fruit puree). The coated microtabs have yellow color, no taste and no smell: do not chew, solubilize or pulverizing to avoid lose this characteristic.

NUTRITIONAL INFORMATION		
Average amount	For 100g of Microtablets	For 14g of Microtablets
Energy	1678 kJ	235 kJ
	396 kcal	55 kcal
Fat	3.6 g	0.50 g
Of which saturated	3.59 g	0.50 g
Carbohydrate	13 g	1.82 g
Of which sugar	0 g	0 g
Fiber	3.7 g	0.52 g
Protein Equivalent	70.8 g	9.9 g
Protein (N*6.25)	73.6 g	10.3 g
Salt	1 g	0.14 g
Aminoacids		
L-aspartic acid (as aspartate)	7.76 g	1.09 g
Glycine	7.68 g	1.08 g
L-alanine	3.07 g	0.43 g
L-arginine	4.90 g	0.69 g
L-cystine	2.01 g	0.28 g

L-glutamine	6.02 g	0.84 g
L-isoleucine	5.31 g	0.74 g
L-histidine	3.07 g	0.43 g
L-leucine	8.27 g	1.16 g
L-lysine	5.50 g	0.77 g
L-methionine	1.42 g	0.19 g
L-proline	5.54 g	0.78 g
L-serine	3.42 g	0.48 g
L-tyrosine	7.78 g	1.09 g
L-threonine	5.31 g	0.74 g
L-tryptophan	1.65 g	0.23 g
L-valine	6.13 g	0.86 g
Taurine	0.12 g	17 mg
L-carnitine	0.08 g	11.3 mg
Total aminoacids	85 g	11.8 g
Equal to equivalent protein*	70.8 g	9.9 g

* *equivalent protein = aminoacids/1,2*

Important notice: the product must be given under strict medical supervision only to the patients with proven PKU. The product is not intended to be used as a sole source of nutrition. Suitable from 3 years of age. For enteral use only. The product may pose health risks if consumed by subjects who do not have the specific disorder for which it is indicated. Keep out of reach of children. Do not assume/administer in case of allergy to one or more ingredients.

Storage: store closed, in a cool and dry place, at temperature below 25°C, away from light, humidity and direct sources of heat. The best before date is referred to the product unopened, properly stored. After open consume the product within a month.

Sales packaging: 4 jar from 110 g

Total content: 440 g

We remind you that information to consumers and product labelling are basically ruled in the European Union by:

- Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, and amendments
- Regulation (EC) No. 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, and amendments
- Regulation (EU) No. 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009

IMPORTANT NOTICE:

Any kind of non-mandatory information is provided on a voluntary basis and under the responsibility of the **business operator** under whose name or business name the food is marketed or, if the operator is not established in the Union, the importer into the Union market according to all relevant current legislation, in particular to Regulation (EU) No. 1169/2011 and Regulation and Regulation (EU) No. 603/2013



QUALITY MANAGEMENT SYSTEM
UNI EN ISO 9001:2015
UNI CEI EN ISO 13485:2016
CERTIFIED BY CERTIQUALITY

COMPANY INSPECTED BY CERTIQUALITY
FOR THE COMPLIANCE TO
GMP
CODE OF FEDERAL REGULATION,
TITLE 21, VOLUME 2, PART 111



If in the case and under specific agreement, Labomar shall be committed to check the artworks (carton box and/or label) **only** with respect to the data herein described.

If the product is intended for sale in markets outside EU, the business operator under whose name or business name the product will be sold, is responsible for complying with regulatory and labelling requirements in the destination country.