



PKU **GOLIKE**

JOIN THE EVOLUTION

PKU GOLIKE is a **next-generation medical food** for children and adults with phenylketonuria (PKU).



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or learn more at: [PKUGOLIKEHCP.com](https://www.PKUGOLIKEHCP.com)

Relief Therapeutics products are medical foods for the dietary management of phenylketonuria (PKU) and must be used under medical supervision.

Many patients with PKU struggle to adhere to their diet and medical foods¹

Medical foods often have unpleasant flavor and aftertaste²

- Free amino acids (AAs) commonly found in medical foods have a strong smell and flavor, often leading to **bad breath and an unpleasant aftertaste**³
- Moreover, many patients report "**taste fatigue**" with their current medical food since it must be consumed multiple times a day, every day, for life^{3,4}

Other common barriers to adherence include:

Large volumes of liquid³



GI dysfunction³



Food restrictions⁵



Social issues (ie, bad breath)⁵



Even in patients with PKU who adhere to their diet, issues may remain

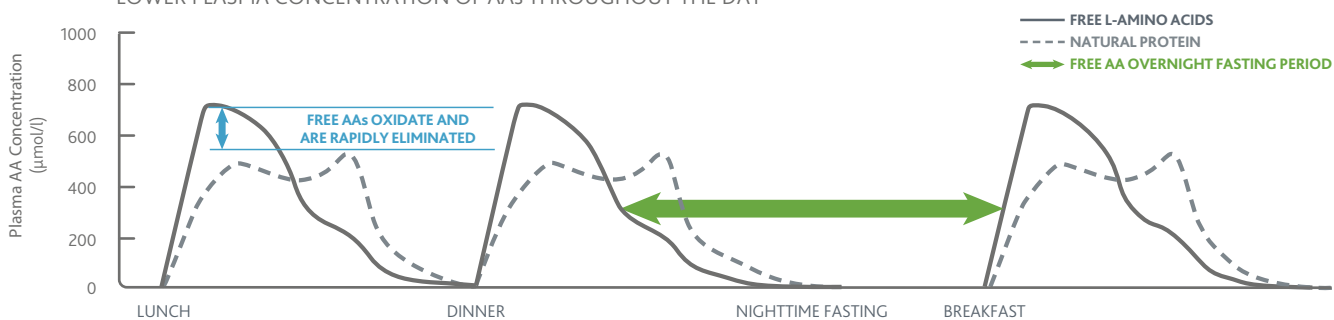
Patients with PKU remain at increased risk for mood and cognitive disorders, even when adherent^{3,6}

Neurological issues include:

- Reduced executive function
- Psycho-social problems like anxiety and depression

The **quick absorption time** of free AAs results in **rapid AA oxidation and elimination**. This can lead to **low plasma concentration of AAs for extended periods of time**, particularly overnight.²

WITH FREE AAs, FAST ABSORPTION MEANS LONGER PERIODS OF LOWER PLASMA CONCENTRATION OF AAs THROUGHOUT THE DAY^{2,7}



Adapted from Gropper and Acosta, *JPEN*, 15; 48-53, 1991.

Periods of low plasma AA concentration levels may cause muscle to break down

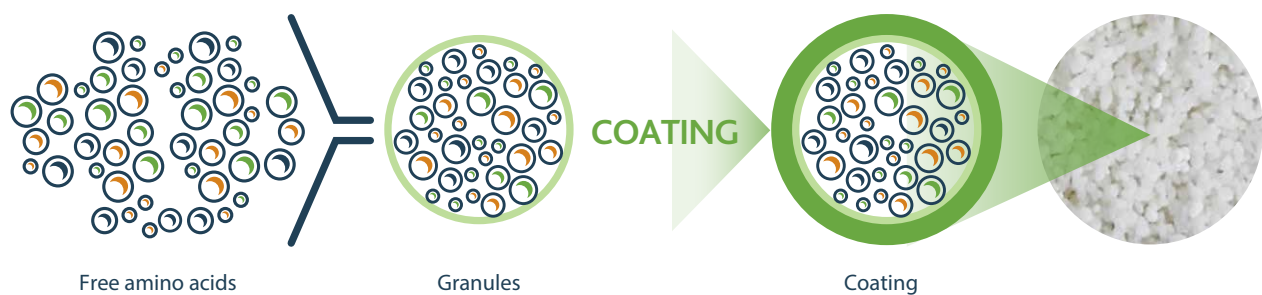
- During the extended fasting periods at night, patients may experience catabolic episodes where **muscle breaks down, releasing Phe** into the bloodstream and raising Phe levels⁸
- Elevated or fluctuating Phe levels are the **primary cause of neurological dysfunction** in patients with PKU^{3,8}

The PKU GOLIKE difference: An innovative, plant-based coating for free AAs

PKU GOLIKE's amino acids (AAs) are coated with 2 **GRAS (Generally Recognized As Safe by the FDA)** ingredients (sodium alginate and ethyl cellulose), turning them into prolonged-release granules.^{1,9}

This process, powered by Physiomimic Technology™, helps **mimic the absorption rate** of natural proteins, while **masking the aftertaste and odors** of free AAs.¹

A look at Physiomimic Technology™



In the lab:



Free AAs are coated with 2 plant-based ingredients¹

In the body:



The coating acts as a barrier, helping to ensure prolonged release and physiological absorption in the patient's intestines¹

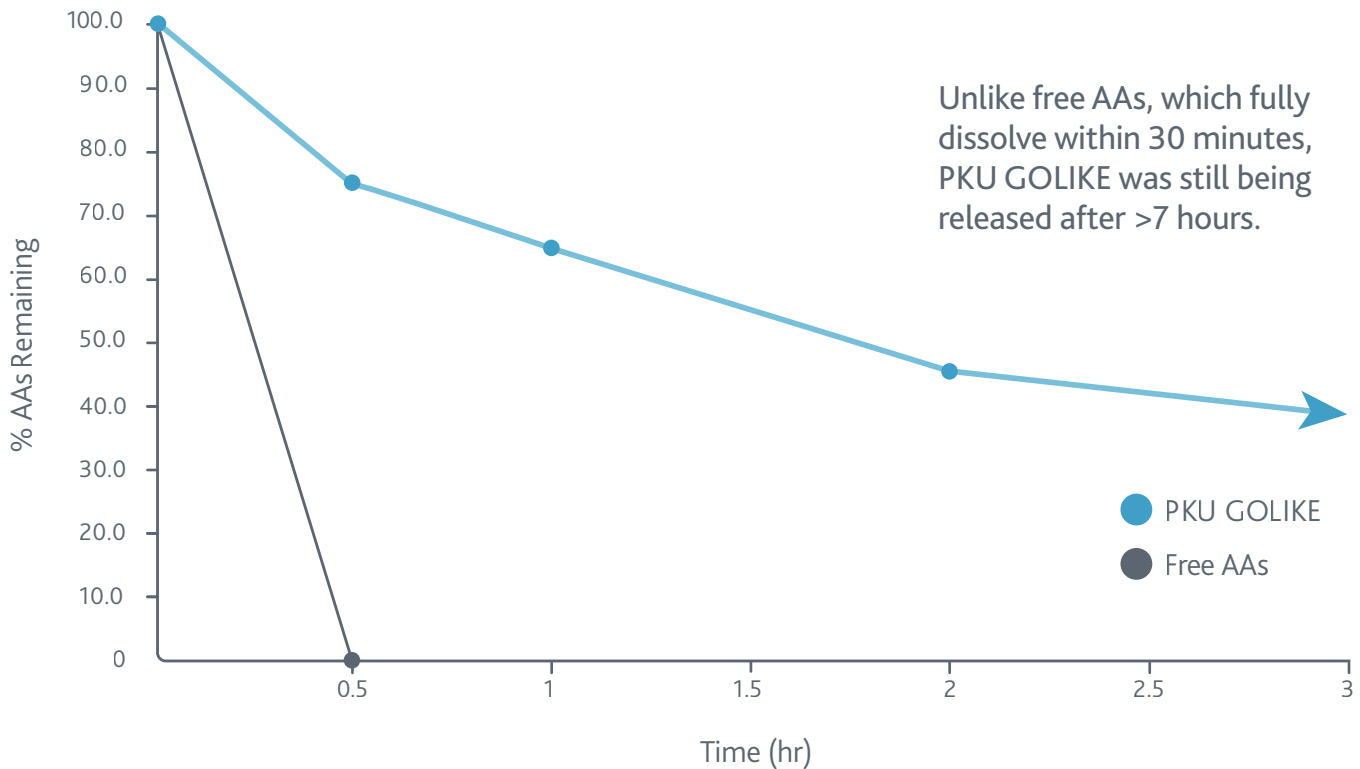


Scan to see a video of the science
behind PKU GOLIKE

A step forward in medical foods

PKU GOLIKE enables a **more physiological absorption of AAs** that may help patients achieve better metabolic control.^{1,3}

More gradual dissolution profile of PKU GOLIKE vs free amino acids in vitro¹



Higher EAA plasma concentrations after 7 hours¹⁰

Higher EAA plasma concentrations could **reduce catabolic episodes** and keep Phe levels under control throughout the day. In a clinical study, PKU GOLIKE provided higher EAA plasma concentrations after 7 hours vs free AAs in healthy volunteers. ($P < 0.01$)

Designed with your patients in mind

PKU GOLIKE packets contain prolonged-release AAs that are both **100% Phe-free** and **absorbed at rates closer to that of natural protein**¹:

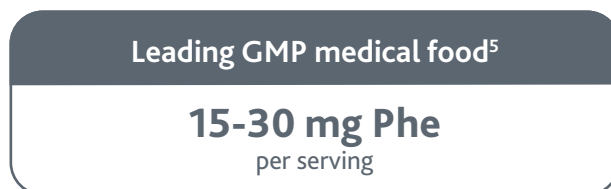
- **No flavor of its own.** The AAs in PKU GOLIKE are coated to mask the taste of free AAs and won't leave an aftertaste or cause bad breath¹
- **May reduce GI symptoms.** Unlike free AAs, PKU GOLIKE does not need to be consumed with large volumes of liquid and has not been shown to cause GI dysfunction^{1,3}
 - In an observational study of PKU GOLIKE, fewer patients with PKU reported burping, flatulence, and regurgitation compared to their previous medical food^{3*}

*As shown in a 7-day prospective, observational study of children aged 3-16 with PKU (n=7). A majority (5 of 7) recorded lower Phe levels and fewer GI symptoms (4 of 7). No cases of mild, moderate, or severe diarrhea, constipation, bloating/distention, nausea, or vomiting were reported.³



PKU GOLIKE gives patients with PKU all the amino acids they need, with 0 Phe^{11,12}

Less Phe in your patients' medical food may give them more flexibility with their diet^{11,12}



Daily Phe savings may be equivalent to a serving of potato[†] (45 to 90 mg of Phe)
Assuming 3x servings of medical food a day.

[†]1/2 cup of potato (~65 mg of Phe).

Many patients can benefit from PKU GOLIKE

PKU GOLIKE is specially formulated to help **children, teens, and adults** with PKU, wherever they are on their journey.^{11,12} Here are some examples of patients:

Women who are family planning



Mary: Teacher
Age: 28

Medical history:

- Average weight and BMI

Desired product:

- Prefers ingredients that are plant-based and considered safe for pregnant women
- Easier to adopt with no odor or flavor, since she is not used to medical food

PKU management history:

- Returning to diet

Teenagers



John: In high school
Age: 17

Medical history:

- Average weight and BMI

Desired product:

- Concerned about having bad breath and GI symptoms, which may cause social issues

PKU management history:

- Has switched medical foods a couple of times due to social concerns
- Recently has encountered adherence issues

Young children



Tom: Kindergarten student
Age: 5

Medical history:

- Higher BMI

Desired product:

- Convenient option that is pre-packaged, pre-measured, and easy to take at school
- Prefers a formula that doesn't need a large volume of liquid and is low-calorie

PKU management history:

- Has been on the same medical food since birth
- Has high protein tolerance and large appetite

100% Phe-free, convenient nutrition for children and adults with PKU^{11,12}

PKU GOLIKE^{8,11,12}:

Contains all **19 AAs** that patients with PKU need to maintain neurological and muscular health

Fortified with **27 essential vitamins and minerals**, including ones normally found in protein-rich foods like iron, calcium, and vitamin B12

Freedom to travel^{11,12}

PKU GOLIKE packets are easy to carry and **meet TSA requirements**, so your patients can slip them into their purse, backpack, or carry-on to enjoy convenient medical food throughout their journey

Free of^{11,12}:



Phe



Lactose



Gluten

- Not derived from milk or whey products
- Low-calorie, low-carb, and naturally sugar-free
 - Under 100 calories and only 3.5 grams of carbs per serving

Medical food for every patient

PKU GOLIKE packets are pre-measured so patients with PKU can get the right nutrients for their age.

Children

- For patients ages 4 to 16
- ~2 ½ tablespoons of granules per packet
- 15 g of protein equivalent per packet^{12*}



Scan to see
full nutritional details



Pack size: 30 x 24 g packets

Adults

- For patients ages 16+
- ~3 ½ tablespoons of granules per packet
- 20 g of protein equivalent per packet^{11*}



Scan to see
full nutritional details



Pack size: 30 x 31.5 g packets

*1 g of protein equivalent=1.2 g of amino acids.
The protein content is provided by the amino acids.

Must only be used under medical supervision. For oral feeding. Not for parenteral use. Not suitable as a sole source of nutrition. Do not use in case of known or suspected allergy and/or intolerance to one or more of the ingredients.

Tips for making the most of PKU GOLIKE

PKU GOLIKE can be mixed with a wide assortment of foods that your patients already enjoy. But to help them have the best experience, here are 5 tips to share:

<p>Try foods with texture^{11,12}</p>	<p>The granules, by design, aren't supposed to dissolve. Mix with soft creamy foods, such as thick smoothies, applesauce, or pasta sauce (room temperature or cooler)</p>
<p>Start slow</p>	<p>Acclimate to the texture of the granules by initially mixing 1/3 of a packet into foods and working up to a full packet over a couple of weeks</p>
<p>Avoid heat^{11,12*}</p>	<p>Avoid cooking granules and only mix them in meals that are room temperature or cooler</p>
<p>Eat normally, but promptly^{11,12}</p>	<p>Don't chew the granules. But they should be consumed right after mixing to preserve their integrity</p>
<p>Use within 24 hours^{11,12}</p>	<p>Opened packets should be stored in an airtight container and can be used to prepare more than one meal within 24 hours</p>

*Keep below 77°F and avoid moisture, direct light, and heat.



Scan to see recipes to share



Ordering made easy through our exclusive distributor: Pentec Health®

To order PKU GOLIKE, **FAX 866-869-9442** or **EMAIL PKUGOLIKEORDERS@pentechealth.com** the following information:

- PKU GOLIKE Pentec Health written order form
- Patient's demographics
- Patient's insurance information
- Letter of medical necessity
- Patient's chart notes



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Download letter of medical necessity



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The PKU GOLIKE difference

Prolonged-release granules¹

- An **innovative, plant-based coating** turns free AAs into prolonged-release granules, masking their taste and allowing for **absorption rates more similar to natural proteins**

100% Phe-free^{8,11,12}

- PKU GOLIKE packets are fortified with **27 vitamins and minerals** and the 19 AAs that patients with PKU need to maintain neurological and muscular health. And all with **0 Phe**

Designed for better metabolic control^{1,3}

- PKU GOLIKE's more physiological absorption rate may help **maintain plasma EAA concentrations for longer** and result in more efficient usage of AAs

References: 1. Giarratana N, Gallina G, Panzeri V, et al. A new Phe-Free protein substitute engineered to allow a physiological absorption of free amino acids for phenylketonuria. *JIEMS*. 2018;6:1-9. 2. Scheinin M, Junnila J, Reiner G, et al. Nitrogen balance after the administration of a prolonged-release protein substitute for phenylketonuria as a single dose in healthy volunteers. *Nutrients*. 2021;13(3189):1-10. doi:10.3390/nu13093189 3. MacDonald A, Ashmore C, Daly A, et al. An observational study evaluating the introduction of a prolonged-release protein substitute to the dietary management of children with phenylketonuria. *Nutrients*. 2020;12(2686):1-11. doi:10.3390/nu12092686 4. MacDonald A, van Rijn M, Feillet F, et al. Adherence issues in inherited metabolic disorders treated by low natural protein diets. *Ann Nutr Metab*. 2012;61(4):289-295. 5. Ney DM, Gleason ST, van Calcar SC, et al. Nutritional management of PKU with glycomacropeptide from cheese whey. *J Inherit Metab Dis*. 2009;32(1):32-39. doi:10.1007/s10545-008-0952-4 6. Enns GM, Koch R, Brumm V, et al. Suboptimal outcomes in patients with PKU treated early with diet alone: Revisiting the evidence. *Mol Genet Metab*. 2010;101(2-3):99-109. 7. Gropper SS, Acosta PB. Effect of simultaneous ingestion of l-amino acids and whole protein on plasma amino acid and urea nitrogen concentrations in humans. *JPEN*. 1991;15(1):48-53. 8. Giarratana N, Giardino L, Bighinati A, et al. In Vivo Metabolic Responses to Different Formulations of Amino Acid Mixtures for the Treatment of Phenylketonuria (PKU). *Int J Mol Sci*. 2022;23(2227):1-12. doi:10.3390/ijms23042227 9. Food Additive Status List. August 25, 2022. Accessed September 14, 2022. <https://www.fda.gov/food/food-additives-petitions/food-additive-status-list> 10. Scheinin M, Barassi A, Junnila J, et al. Amino acid plasma profiles from a prolonged-release protein substitute for phenylketonuria: a randomized, single-dose, four-way crossover trial in healthy volunteers. *Nutrients*. 2020;12(1653):1-16. doi:10.3390/nu12061653 11. PKU GOLIKE Plus 16+ Technical Sheet. Relief Therapeutics, 2022. 12. PKU GOLIKE Plus 4-16 Technical Sheet. Relief Therapeutics, 2022.



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