

KETOCAL® 3:1 UPDATED FORMULATION, SAME TRUSTED RATIO – COMING SPRING 2021



FAQS FOR FAMILIES



Does your family use KetoCal 3:1 Powder? If so, we wanted to let you know about some minor changes coming soon.

Rest assured that the upcoming changes to KetoCal 3:1 Powder are small and do not affect the 3:1 ketogenic ratio. Below are some questions that you might have and the answers to them.

If you have any further questions about the changes to KetoCal 3:1, please feel free to contact our Nutrition Services team at 1-800-365-7354. If you have any questions about your prescribed intake of KetoCal 3:1 and how that may be affected by these changes, please reach out to your healthcare provider.

What is KetoCal 3:1 and who uses KetoCal 3:1?

KetoCal 3:1 is a medical ketogenic formula specifically designed for patients with intractable epilepsy.

It has a set ketogenic ratio 3:1 (grams of fat: grams of carbohydrates + protein) and contains DHA & ARA. KetoCal 3:1 is nutritionally complete and indicated for individuals over 1 year of age.

What are the updates to KetoCal 3:1?

KetoCal 3:1 is available in many countries. Given changes to European regulations, we are making some adjustments to the KetoCal 3:1 recipe. This includes changes to the macronutrient (carbohydrate, fat and protein), as well as the vitamin and mineral profile. The changes will not affect the ketogenic ratio of the product.

What are the changes to KetoCal 3:1?

The adjusted recipe for KetoCal 3:1 will include minor changes to the levels of macronutrients (carbohydrate, fat and protein), as well as the levels of certain vitamins and minerals. The changes will not affect the ketogenic ratio of the product.

When will this change occur?

The updated formulation of KetoCal 3:1 will be available in the Spring of 2021 (we expect around April).

Why are these changes occurring?

KetoCal 3:1 is available in many countries and we ensure compliance with applicable laws in the countries where our products are sold. Given recent changes to European regulations, we made some minor adjustments to nutrient levels in KetoCal 3:1.

Is the ketogenic ratio changing?

No, the updated KetoCal 3:1 will remain at a 3:1 ketogenic ratio. There will be small changes to the levels of macronutrients (specifically fat and protein) per 100 grams of powder but the overall ketogenic ratio of the product will not change. You can view the updated nutritional information at the end of this document (appendix 1)

Have the calories changed?

Yes, the calories per gram and calories per can of KetoCal 3:1 will change slightly. The current version of KetoCal 3:1 provides 699 calories per 100 grams of powder, while the updated version will provide 711 calories per 100 grams of powder. Therefore, each can of the current KetoCal 3:1 provides 2,097 calories and each can of the updated KetoCal 3:1 will provide 2,133 calories. Talk with your ketogenic dietitian to determine if your intake and/or monthly prescription needs to be adjusted to account for this minor difference in the calories.

Have the macronutrients (carbohydrate, fat and protein) changed?

Yes, there are small changes to the amount of fat and protein per 100 grams of KetoCal 3:1 powder. The changes will not affect the ketogenic ratio of the product.

Have the levels of vitamins and minerals changed?

Yes, the levels of specific vitamins and minerals have changed slightly. The updated nutritional information is available at the end of this document (appendix 1)

KetoCal 3:1 is suitable as a sole source of nutrition for children aged 1-3 years of age or supplemental nutrition for individuals over 1 year of age depending on the age, weight, energy needs and medical condition of the individual.

Is the updated KetoCal 3:1 nutritionally complete?

Yes, the updated KetoCal 3:1 can be used to provide complete nutrition for children ages 1-3 or can be used to provide supplemental nutrition for ages 1 and up. If you have any questions about how this product fits into your child's medical ketogenic diet, please reach out to your healthcare provider.

Why is the label different?

We regularly review and update the look and packaging of our products. We hope you like the new look of KetoCal 3:1!

How do I know if I have the updated version of KetoCal 3:1 or not?

You will be able to tell if you have the updated version of KetoCal 3:1 by the label. You can view the current and updated versions of the KetoCal 3:1 label below.

CURRENT FORMULATION



UPDATED FORMULATION



Are the mixing instructions different? Do I need a new recipe?

The mixing instructions are the same. There are minor changes to the recipe in the amount of powder needed as shown in the table below. Check with your dietitian to see if you need a new recipe. A gram scale is necessary to accurately measure KetoCal 3:1 powder.

Calories/fl oz	Osmolality, mOsm/kg	Calories/mL	KetoCal 3:1 powder, g	Water, mL	Final volume, mL
20	100	0.66	9.3	90	100
24	120	0.8	11.3	89	100
30	150	1.0	14.1	86	100

Does the new product taste/smell different?

There are no major changes to the taste/smell of the updated product. You may notice a slightly darker color of the powder in the updated formulation.

Are there any ingredient changes?

Yes, you may notice a few new additions to the ingredient list. They are magnesium chloride (which is the source of magnesium) and glycine, which is an amino acid. There are also some ingredients that are no longer in KetoCal 3:1 powder, primarily soy lecithin. There are other micronutrients that have changed sources but KetoCal 3:1 will still meet micronutrient needs dependent on age, weight, energy need, and medical condition of the individual.

What should I do to prepare for this change?

We recommend that you speak with your healthcare provider to determine if any changes need to be made to your daily intake or monthly prescription of KetoCal 3:1 to account for these minor changes in the formulation.

Do I need to transition and if so, how?

For most children, they will be able to consume the updated KetoCal 3:1, without a transition period. If your child is especially sensitive to any minor changes in the diet, you may want to gradually switch to help ensure a smooth transition. If so, you might start with $\frac{1}{4}$ renovated product and $\frac{3}{4}$ previous product for a few days, then go to $\frac{1}{2}$ and $\frac{1}{2}$ for a few days, then $\frac{3}{4}$ and $\frac{1}{4}$, until you reach 100% of the renovated product. The exact quantities to prepare will vary since each family has different instructions from the dietitian as to how to prepare the KetoCal. We are happy to help you calculate the amounts required to transition this way. Please call our Nutrition Services Department at 1-800-365-7354. Before making any changes, please always check with your dietitian.

How do I get KetoCal 3:1? Will there be any changes to how I or my clinic orders KetoCal 3:1?

There will be a change to the Nutricia ordering code used for KetoCal 3:1, which will be the following:

	Product name	Product code	Packaging	UPC - case	UPC - unit	NDC* format code	HCPCS Code
Current	KetoCal 3:1	16672	6 X 300g (11 oz)	7497351-66727	7497350-66720	49735-0166-72	B4154
New (April 2021)	KetoCal 3:1	77155	6 X 300g (11 oz)	7497351-71554	7497350-71557	49735-0171-55	B4154

*Nutricia North America does not represent these codes to be National Drug Codes (NDCs). NDC-format codes are product codes adjusted according to standard industry practice to meet the format requirements of pharmacy and health insurance systems.

You or your clinic can still call us at 1-800-365-7354 or go online (<https://shop.myketocal.com/product/ketocal-31>) to order KetoCal 3:1 or request samples. You will start receiving this updated product in April 2021.

How do I learn more? What if I have other questions?

Please let us know if there are any questions. You can contact our Nutrition Services Team via email at NutritionServices@Nutricia.com or by calling 1-800-365-7354, Monday-Friday 8:30 a.m. to 5:00 p.m. ET.

Contact your healthcare team prior to making any potential changes to your medical ketogenic diet or if you have any questions about your or your loved one's diet.

APPENDIX 1: NUTRIENT COMPARISON CHART

KetoCal 3:1 is suitable as sole source of nutrition for children aged 1-3 years old or as supplemental nutrition for children over 1 year of age, depending on the weight, energy needs and medical condition.

	Current KetoCal 3:1 per 100 g	Updated KetoCal 3:1 per 100 g	Current KetoCal 3:1 per 100 kcal	Updated KetoCal 3:1 per 100 kcal
Calories	699	711	100	100
Protein, g	15.3	15.4	2.2	2.2
Carbohydrate, g	7.2	7.2	1.0	1.0
Fat, g	67.7	68.6	9.7	9.7
Saturated, g	25.5	26.6	3.6	3.7
Monounsaturated, g	22.3	24.0	3.2	3.4
Polyunsaturated, g	16.6	18.0	2.4	2.5
Linoleic Acid, mg	12700	15515	1817	2183
α -Linolenic Acid, mg	1270	1284	182	181
DHA, mg	116	180	16.6	25.0
ARA, mg	116	180	16.6	25.0
VITAMINS				
Vitamin A, IU (mcg RE)	1748 (525)	1166 (350)	250 (75.1)	164 (49.3)
Vitamin D ₃ , IU (mcg)	508 (12.7)	613 (15.3)	72.7 (1.8)	86.3 (2.2)
Vitamin E, IU (mg α -TE)	11.8 (7.9)	12.1 (8.1)	1.7 (1.1)	1.7 (1.1)
Vitamin K, mcg	55.9	49.8	8.0	7.0
Thiamin, mg	0.89	0.64	0.13	0.09
Riboflavin, mg	0.70	0.64	0.10	0.09
Vitamin B ₆ , mg	0.70	0.64	0.10	0.09
Vitamin B ₁₂ , mcg	1.4	1.26	0.20	0.18
Niacin, mg	4.9	4.5	0.70	0.63
Folic Acid, mcg	140	95.8	20.0	13.5
Pantothenic Acid, mg	2.8	5.4	0.40	0.76
Biotin, mcg	13.9	12.8	2.0	1.8
Vitamin C, mg	84.0	59.0	12.0	8.3
Choline, mg	180	202	25.8	28.5
Inositol, mg	153	140	21.9	19.7
MINERALS				
Calcium, mg	760	729	109	103
Phosphorus, mg	510	492	73.0	69.2
Magnesium, mg	95.0	70.3	13.6	9.9
Iron, mg	10.9	10.9	1.6	1.5
Zinc, mg	7.4	7.7	1.1	1.1
Manganese, mg	0.57	0.13	0.08	0.02
Copper, mcg	760	460	109	64.7
Iodine, mcg	124	93.5	17.7	13.2
Molybdenum, mcg	31.3	31.4	4.5	4.4
Chromium, mcg	26.2	26.1	3.7	3.7
Selenium, mcg	18.9	24.3	2.7	3.4
Sodium, mg	287 (12.5)	320 (13.9)	41.1 (1.8)	45.0 (2.0)
Potassium, mg	900 (23.0)	828 (21.2)	129 (3.3)	117 (3.0)
Chloride, mg	440 (12.6)	491 (13.8)	62.9 (1.8)	69.1 (1.95)
L-Carnitine, mg	48.0	43.9	6.9	6.2
Taurine, mg	48.0	43.8	6.9	6.2