

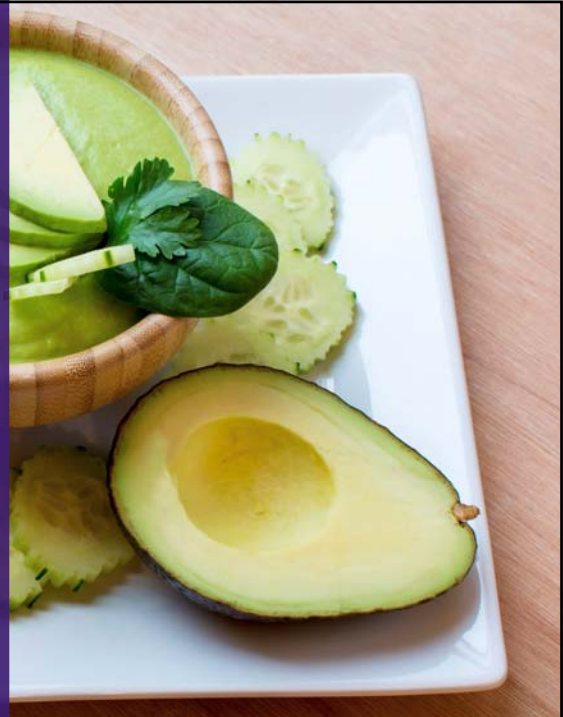


KetoCal® 2.5:1

A new medical food to manage your adult and older children on the ketogenic diet

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KetoCal is a medical food and is intended for use under medical supervision.



Webinar objectives

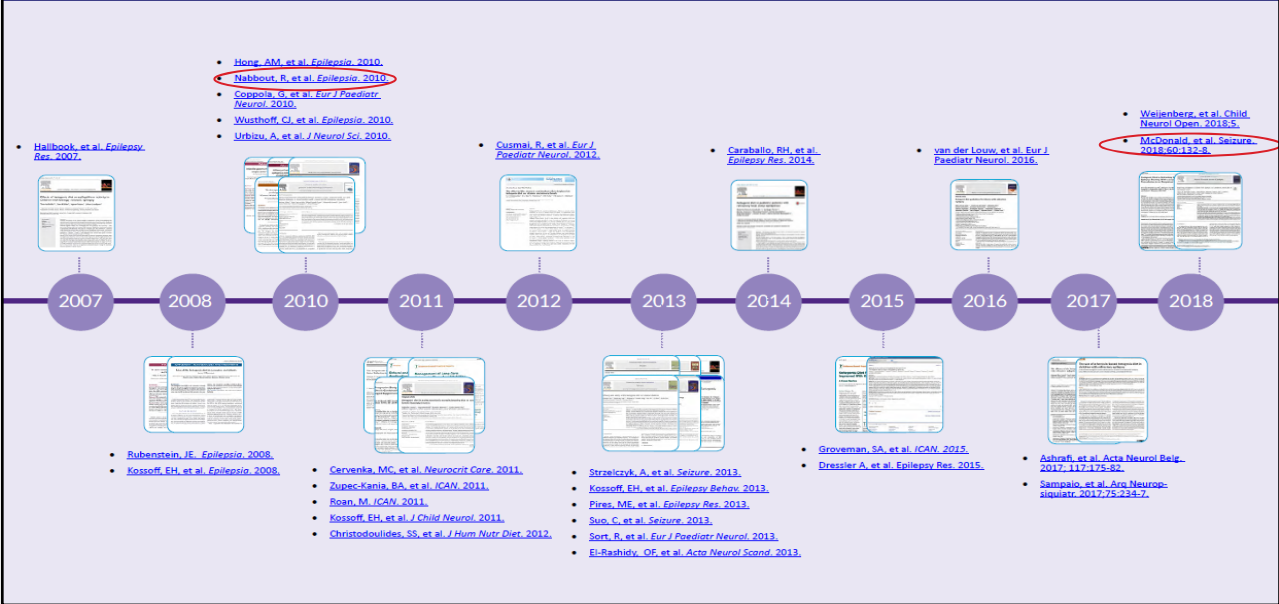


- Review KetoCal history and evidence
- Understand how the new KetoCal 2.5:1 fits in your patients' epilepsy management plan
- Discover the benefits and key nutritional components of the new KetoCal 2.5:1 for your patients

KetoCal heritage spans 18 years




Extensive body of evidence supporting the use of KetoCal

Nabbout, et al. *Epilepsia*. 2010;51:2033-7.



- 9 children at 5 centers, aged 54-98 months (4 ½ years-8 years, 2 months)
- Admitted with status epilepticus → placed on a 4:1 ketogenic diet
- Ketonuria reached within 2-4 days – 1 patient failed to reach ketonuria 2/2 to steroids
- Seizures managed in 7/8 patients after onset of ketonuria within 2-4 days (mean 2 days) and 4-6 days (mean 4.8 days) following onset of diet initiation
- KD failed to manage seizures in 2 patients – 1 2/2 steroids
- 6 responders stayed on diet for 6 months – 2 years



Since this was an early study with status epilepticus/FIRES, the final recommendation was for continued studies to be conducted.

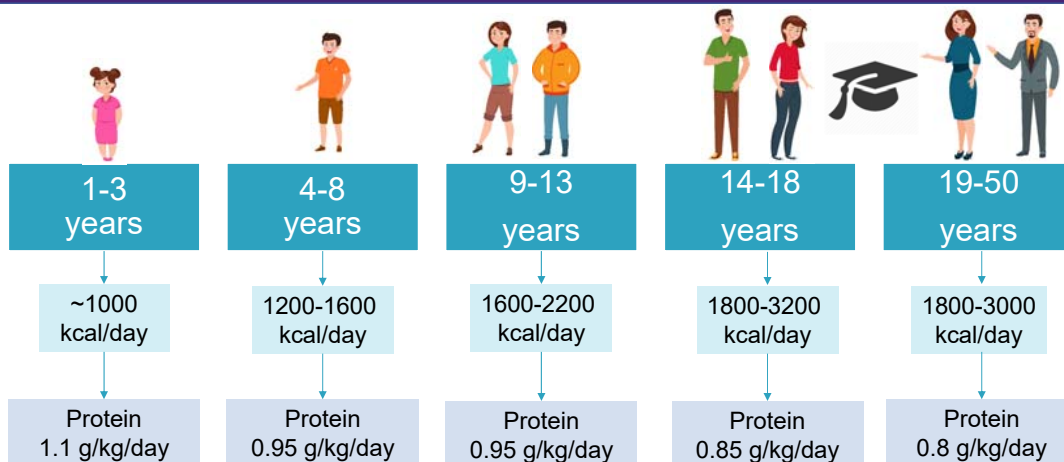
Since that time, more research has been conducted. The latest consensus guidelines published by Kossoff et al in 2018 recommend the ketogenic diet for patients with FIRES and Super-refractory status epilepticus as studies consistently show more than 70% of patients have a >50% seizure reduction.

McDonald, et al. Seizure. 2018;60:132-8.



- Prospective, randomized, crossover study with 80 adults
- All educated on 20 g CHO/day MAD
 - Group 1 started with KetoCal 4:1 LQ, once per day
 - Group 2 started without KetoCal
- After 1 month, Group 1 discontinued KetoCal 4:1 LQ and Group 2 started KetoCal 4:1 LQ, once per day
- 84% of all patients achieved ketosis at a median of 4-4.5 days
- Both groups achieved >50% seizure reduction after 1 month.
- Conclusion: “Although supplementing MAD with a ketogenic formula in the first month did not increase the likelihood of reducing seizure compared to MAD alone, significantly more adults remained on MAD long-term with this approach.”

Nutrition needs vary over time



10M Academies. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Washington, DC: The National Academies Press; 2005
U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015 – 2020 Dietary Guidelines for Americans. 8th Edition

Life changes over time



- Responsibilities as a child
 - School
- Responsibilities as an adult
 - Work
 - School
 - Caretaker
 - Financial



Introducing KetoCal® 2.5:1 LQ with MCT

- ✓ The **first and only** nutritionally complete 2.5:1 ketogenic formula with MCT for refractory epilepsy
- ✓ **Specifically designed** for children over 8 years of age and adults



Let's meet with 3 patients to understand their needs better



Aaron, 14 years old, diagnosed with refractory epilepsy



Emma, 27 years old, diagnosed with refractory epilepsy



Logan, 10 years old, diagnosed with refractory epilepsy



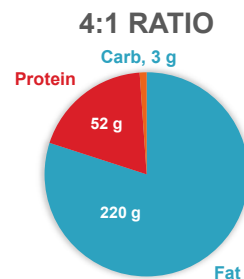
**Aaron is
14 years old.**
He is on a lower ketogenic ratio
to meet his protein needs.

Let's talk about your patients



- Children 14-18 years → 1800-3200 kcal/day
 - Protein: 0.85 g/kg/day
- 14 year old male patient. Weight: 61 kg. Estimated calorie needs – 2200 kcal/day, 52 g protein

- Limited carbohydrate intake

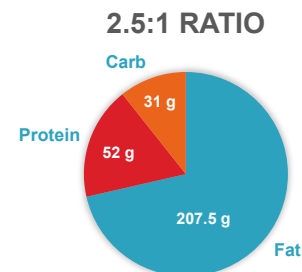


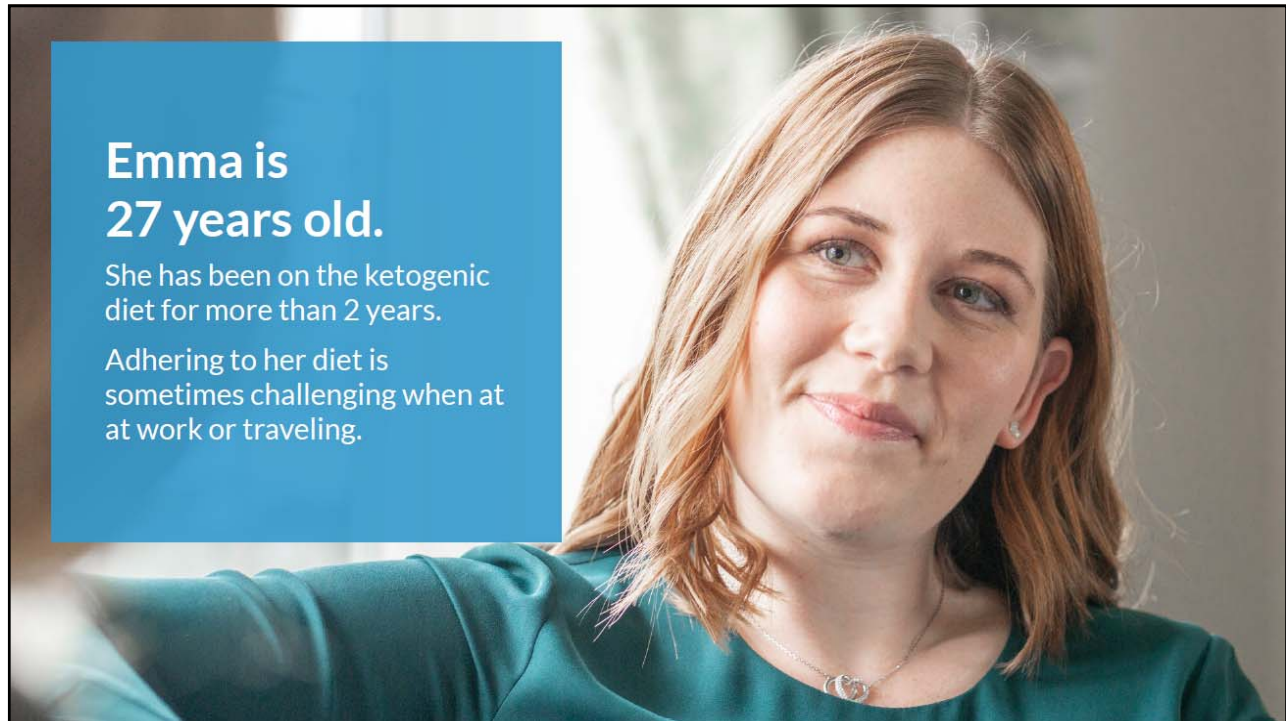
For the same patient



- Children 14-18 years → 1800-3200 kcal/day
 - Protein: 0.85 g/kg/day
- 14 year old male patient. Weight: 61 kg. Estimated calorie needs – 2200 kcal/day, 52 g protein

- Allows adequate protein intake, with more carbohydrate than a 4:1 ratio





Convenience



- ❑ Breakfast smoothie
- ❑ Snack time
- ❑ Stuck in traffic?
- ❑ Social gatherings



Logan is tube fed and orally fed.

His mom has been mixing several formulas and adapting recipes. It gives her peace of mind knowing that KetoCal can meet his nutrition needs.



Ensuring accurate mixing can be a main concern of caregivers



- Mixing multiple formulas takes time for the caregiver and can be a complex process.



- **Errors might happen** which can lead to unintentional ratio changes and changes in nutrient intake.

Mixing multiple formulas is time consuming



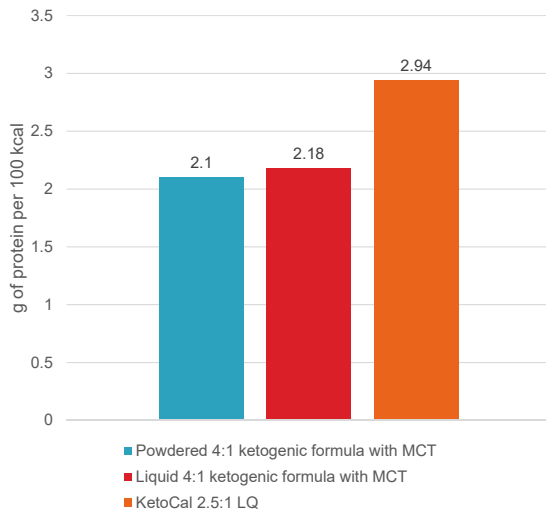
Unique Product Characteristics



- ❑ Higher in protein*
- ❑ Contains MCT Oil
- ❑ Multi-fiber blend
- ❑ Age-specific vitamins and minerals for individuals 8 years and older

*Compared to 3:1 and 4:1 ketogenic formulas

KetoCal 2.5:1 helps meet protein needs

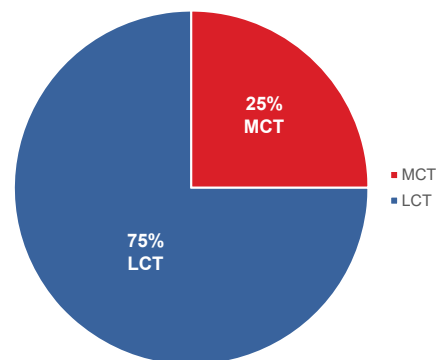


- KetoCal 2.5:1 is higher in protein compared to other ketogenic formulas with added MCTs.
- KetoCal 2.5:1 contains 2.94 g protein/100 kcals or 10.7 g protein/drink box

KetoCal 2.5:1 contains MCT oil



- 33.9 g fat/drink box
- No trans fat
- 25% fat from MCT oil
- Beneficial because MCTs produce more ketones per calorie compared to long chain fats



KetoCal provides fiber



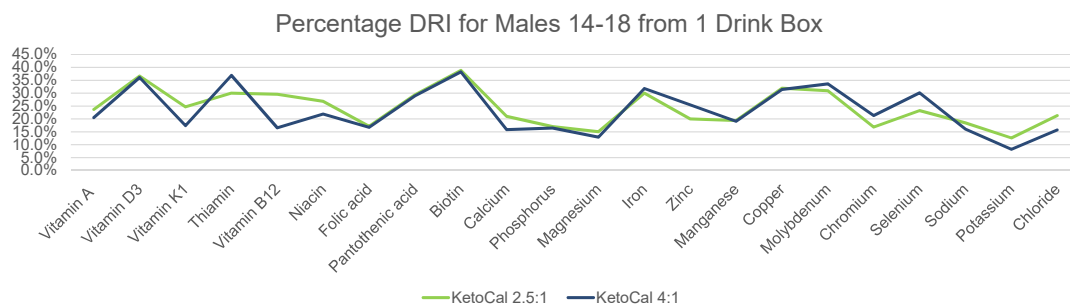
- Each drink box provides 2.6 g of a multi-fiber blend
- Same multi-fiber blend as KetoCal 4:1 products

Dietary Fiber	Soluble	Insoluble	Prebiotic
Microcrystalline cellulose		✓	
Chicory root inulin	✓		✓
Fructooligosaccharide (FOS)	✓		✓
High Amylose Corn Starch		✓	
Soy Fiber		✓	

KetoCal 2.5:1 is nutritionally complete



- Age specific vitamins and minerals
- Can be used as a sole source of nutrition for individuals 8 years and older



Is there clinical data on KetoCal 2.5:1?



- YES!
- Title: Evaluating the Tolerance, Compliance, Acceptability and Safety of KetoCal 2.5:1 LQ, a Nutritionally Complete Liquid Feed for Use as Part of the Ketogenic Diet (KD) in Children 8+ Years, Adolescents and Adults With Intractable Epilepsy or Other Disorders Where the KD is Indicated
- Clinical Trial Number: NCT03196271
- Inclusion Criteria: At least 8 years of age, willing to follow a ketogenic diet for at least 2 months, no other contraindications as stated on the clinicaltrials.gov website

One KetoCal 2.5:1 LQ acceptability study (n=19)* found the following:

96%

compliance was seen among participants taking the prescribed amount of KetoCal 2.5:1 LQ.

74%

of patients/parents/caregivers agreed that KetoCal 2.5:1 LQ was well tolerated.

90%

of dietitians reported that KetoCal 2.5:1 LQ was well tolerated.

The clinical study was conducted in the UK with 19 patients with refractory epilepsy (age: 8 years and older, range 8.5-46.6 years) in 2018. The patients followed the ketogenic diet for 4 weeks without KetoCal 2.5:1, and then KetoCal 2.5:1 was added to the diet for 4 weeks (average 426 mL/day - range 200-900 mL/day).

In the acceptability study, patients who tried KetoCal 2.5:1*:

87%
liked it overall

88%
thought it was easy to use

70%
enjoyed the taste

“

Patients reported:

It was actually really good.

I would drink it with my coffee in the morning.

I always have it in one go, I could easily have more.

I have to take food with me, so KetoCal 2.5:1 is useful.

”



* Number of responses varied by question

What is the difference between KetoCal products ?



	KetoCal 2.5:1	KetoCal 3:1	KetoCal 4:1
Format	Liquid only	Powder only	Powder and liquid
Age indication	8+	1+	1+
Ratio	2.5:1	3:1	4:1
Fat, g per 100 kcal	9.3	9.7	9.8
Contains MCT (yes/no)	Yes	No	No
Protein, g per 100 kcal	2.9	2.2	2.1
Carb, g per 100 kcal	1.4	1.0	1.2
Net Carb, g per 100 kcal	0.7	1.0	0.4
Fiber (yes/no)	Yes	No	Yes
Fiber, g per 100 kcal	0.7	0	0.7
DHA/ARA	DHA only	DHA/ARA	DHA/ARA

How to get KetoCal 2.5:1



- ❑ Directly from Nutricia!
 - ❑ Contact Nutricia Navigator for access and coverage support: 800-365-7354
 - ❑ Buy online at www.myKetoCal.com
- ❑ Contact your DME, wholesaler, or purchasing department
- ❑ HCPCS Code: B4154
- ❑ Not covered by WIC



WIC is a registered service mark of the U.S. Department of Agriculture for USDA's Special Supplemental Nutrition Program for Women, Infants and Children.

References



- ❑ Nabbout, et al. Epilepsia. 2010;51:2033-7.
- ❑ McDonald, et al. Seizure. 2018;60:132-8.
- ❑ IoM Academies. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Washington, DC: The National Academies Press; 2005
- ❑ U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015 – 2020 Dietary Guidelines for Americans. 8th Edition



Questions?

Thank you for attending!

