INCREASED FAT ABSORPTION FROM ENTERAL FORMULA THROUGH AN IN-LINE DIGESTIVE CARTRIDGE IN PATIENTS WITH CYSTIC FIBROSIS

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ABSORPTION AND SAFETY WITH SUSTAINED USE OF RELiZORB EVALUATION (ASSURE) STUDY IN PATIENTS WITH CYSTIC FIBROSIS RECEIVING ENTERAL FEEDING

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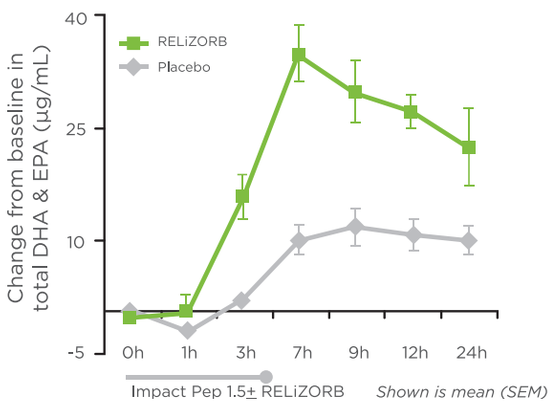
RELiZORB®
(iMMOBILIZED LIPASE) CARTRIDGE

RELiZORB is indicated for use in pediatric patients (ages 5 years and above) and adult patients to hydrolyze fats in enteral formula

RELiZORB NORMALIZES ABSORPTION OF FATTY ACIDS[1,2]

Over 24 hours: Changes in plasma concentrations of DHA and EPA (omega-3 fatty acids)*



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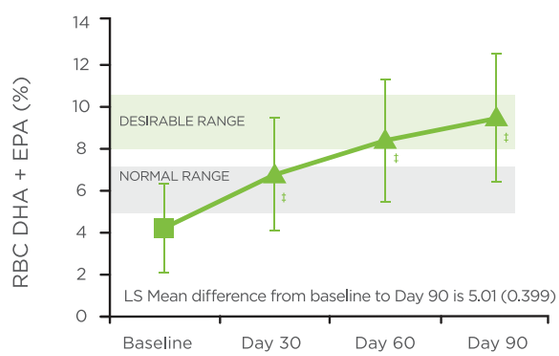
overall increase in total DHA and EPA with RELiZORB versus placebo ($AUC_{0\text{-}24h}$; $P<0.001$)

- DHA and EPA were used as measures in the studies as they are strongly correlated with overall fat absorption[3]

Over 90 days: Changes in Erythrocyte Membrane DHA and EPA Composition (%) also known as Omega-3 Index†[2]



†$P<0.001$ for difference from baseline to Day 30, Day 60, and Day 90.

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increase in red blood cells of DHA and EPA.

Statistically significant increases observed at Day 30, Day 60, and Day 90 ($P<0.001$ for each)[2]

61% of participants demonstrated improvement in weight percentiles[2]

Overall, weight and BMI z-scores and percentiles were not significantly different from baseline to 90 days. However, 20/33 (61%) patients had improvement in weight z-scores and percentiles in the intention to treat (ITT) populations.[2]

In a clinical study, use of RELiZORB was shown to normalize DHA/EPA plasma concentrations to levels consistent with a reference range based on healthy subjects as shown in the literature (please see IFU for full description of the study and references).

USE OF RELiZORB DECREASED THE FREQUENCY OF SOME GI EVENTS[1,2]

57% reduction in the incidence of diarrhea from Period A to Period C[1]

During Period C of the trial, 42% (n=14) of patients using RELiZORB stopped taking PERT capsules during their enteral feeds*[1]

- Despite protocol instructions to maintain their usual treatment practice

In a long-term (90 day) study, sustained use of RELiZORB showed†[2]

- No reported incidences of diarrhea at Day 90
- Overall, the number of particpants reporting GI symptoms decreased from Day 30 to Day 90
- No participants discontinued RELiZORB due to an adverse event

Number of GI events among 33 pediatric and adult patients with CF§

	OVERALL (N=33)	
	PERIOD A PERT	PERIOD C PERT + RELiZORB
ABDOMINAL PAIN	29 (13)	19 (10)
BLOATING	14 (5)	7 (3)
CONSTIPATION	8 (6)	0 (0)
DIARRHEA	**7 (7)**	**3 (3)**
GAS	30 (12)	38 (10)
INDIGESTION/HEARTBURN	9 (6)	4 (3)
NAUSEA	9 (6)	6 (4)
STEATORRHEA/FATTY STOOL	7 (6)	7 (3)
VOMITING	4 (3)	5 (3)
FLATULENCE	1 (1)	7 (1)
SMELLY BURPS	4 (1)	0 (0)
LARGE VOLUME STOOL	0 (0)	4 (2)
ABDOMINAL GAS PAIN	0 (0)	1 (1)
TOTAL FREQUENCY	122	101

Period A=baseline run-in period. Period C=open-label safety period.

DHA=docosahexaenoic acid. EPA=eicosapentaenoic acid. AUC=area under the curve.

PERT = pancreatic enzyme replacement therapy.

*497 study design: A multicenter, prospective, randomized, double-blind, placebo-controlled, cross-over study conducted in 33 patients with cystic fibrosis and a documented history of exocrine pancreatic insufficiency (EPI). Patients were ages 5-34 years and had an a mean duration of enteral nutrition of 6.6 years.

†498 ASSURE study design: A multicenter, prospective, single-arm, open-label study conducted in 36 patients with cystic fibrosis and a documented history of exocrine pancreatic insufficiency. Patients were ages 5-33 years and had a mean duration of enteral nutrition of 6.2 years.

§Gastrointestinal events in Period A vs Period C expressed as number of events (number of patients reporting events).

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497 Study: Journal of Pediatric Gastroenterology and Nutrition, Volume 65, Number 1, July 2017.

498 ASSURE Study: Journal of Pediatric Gastroenterology and Nutrition, Volume 67, Number 4, October 2018.

References: 1. Freedman S, Orenstein D, Black P, et al. Increased fat absorption from enteral formula through an in-line digestive cartridge in patients with cystic fibrosis. *J Pediatr Gastroenterol Nutr.* 2017;65(1):97-101. **2.** Stevens J, Wyatt C, Brown P, Patel D, Grujic D, Freedman SD. Absorption and Safety with Sustained Use of RELiZORB Evaluation (ASSURE) study in patients with cystic fibrosis receiving enteral feeding. *J Pediatr Gastroenterol Nutr.* 2018;Oct;67(4):527-532. **3.** Harris WS, Sands SA, Windsor SL, et al. Omega-3 fatty acids in cardiac biopsies from heart transplantation patients: correlation with erythrocytes and response to supplementation. *Circulation.* 2004;110:1645-1649.

RELiZORB is for use with enteral feeding only; do not connect to intravenous or other medical tubing. Medications should not be administered through RELiZORB. Please see Instructions For Use for full safety information at www.relizorb.com.

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Patents: http://www.alcresta.com/patents

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