INTERNAL USE ONLY



CHALLENGED GROWTH CATEGORY

SUPERIORITY CLAIMS DATABASE (HCP)

DANONE
ONE PLANET. ONE HEALTH

THE SUPERIORITY CLAIMS DATA BASE → DRIVING 360-DEGREE SUPERIORITY

- The competitive landscape is getting tougher, and driving superiority across our portfolio has never been more important
- This database is a tool for countries, in which they will find 360-degree superiority claims across all portfolio that can support building strong activation campaigns. All claims are grouped under:
  - **EFFICACY & OTHER FUNCTIONAL CLAIMS** → FROM SCIENTIFIC PUBLICATIONS (OWNABLE) REVIEW
  - **MARKET POSITION CLAIMS** → FROM MARKET PERFORMANCE DATA
  - **BRAND EQUITY CLAIMS** → FROM QUANT MARKET RESEARCH DATA (REPRESENTATIVE FOR EUROPE)
  - **HERITAGE CLAIMS** → FROM OUR HISTORY & COMPANY VISION
  - **UX & SUSTAINABILITY CLAIMS** → FROM PACKAGING GUIDELINES & SENSORY DATA (COMING SOON)
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- This document and its claims are intended for health care professionals
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OUR PORTOFOLIO SERVES A WIDE RANGE OF NEEDSTATES

FALTERING GROWTH (HCP DRIVEN)

tube/ons infant



Disease or non-disease related malnutrition
0 – 18 mths

tube kids



Disease related malnutrition
1 yr +

ons kids



Disease or non-disease related malnutrition
1 yr +

GROWTH/EATING CONCERNS (CONSUMER DRIVEN)

growth concerns



Concern of flattening height/weight gain
1 yr +

picky eaters



Limited variety in the diet with nutritional inadequacies
1 yr +

PLEASE CLICK ON THE TOPIC THAT YOU'D LIKE TO ACCESS THE CLAIMS

E
EFFICACY & OTHER FUNCTIONAL CLAIMS

tube/ons infant	INFATRINI
	INFATRINI PEPTISORB
ons kids	FORTINI/NUTRINIDRINK MF 1.0/1.5
	FORTINI/NUTRINIDRINK COMPACT MF
growth / eating concerns	GROWTH/EATING CONCERNS
tube Kids	NUTRINI RANGE
	NUTRINIMAX RANGE
	NUTRINI PEPTISORB RANGE

M
MARKET POSITION CLAIMS

B
BRAND EQUITY CLAIMS

H
HERITAGE CLAIMS

U
UX CLAIMS



E

EFFICACY & OTHER FUNCTIONAL CLAIMS

INTERNAL USE ONLY

FALTERING GROWTH
HCP DRIVEN

tube/ ons infant



FALTERING GROWTH

tube/ons infant



efficacy & other functional claims

INFATRINI & INFATRINI PEPTISORB RANGE – EVIDENCE OVERVIEW



*Must be used under medical supervision after consideration of all feeding options, including breast feeding options

FALTERING GROWTH

tube/ons infant

Infatrini



Infatrini OUTCOMES

OUTCOMES RELATED TO **GROWTH**





OUTCOMES RELATED TO **HEALTH ECONOMICS**

OUTCOMES RELATED TO **NUTRITIONAL INTAKE**





OUTCOMES RELATED TO **TOLERANCE**

OUTCOMES RELATED TO **LENGTH OF STAY**





OUTCOMES RELATED TO **IMMUNE SYSTEM**

INFATRINI CLAIMS - GROWTH

This study includes children with congenital heart disease (CHD)

	RESULTS	REFINED CLAIMS
Zhang et al., Nurs Crit Care 2018	**Test group**: Infatrini **Control group**: Energy supplemented Std IF Infants who received HIF showed less weight loss than those who received standard formula −16 g [95% CI: −74 to 42] versus −181 g (95% CI: −264 to −99), P =0·001.	• Following CHD surgery infants receiving Infatrini lost **91% less weight** compared to those receiving a standard feed (p = 0.001) • Following CHD surgery infants receiving a standard IMF lost **more than 10 times** the amount of weight compared to those receiving Infatrini (p = 0.001)
Sheeffer et al., JPEN 2019	**Test group**: Infatrini **Control group**: Std IF Although the mean daily weight gain was higher in the intervention group, with a mean of 16 g/d compared with 10 g/d in the control group, this difference was not statistically significant (P = 0.32).	• **60% more weight gain** per day with Infatrini (p = 0.32)
Eveleens et al. J Hum Nutr Diet 2019	**Single arm study**: Infatrini Weight gain was achieved in 93% of infants, whereas in 71% an increase in WFA z-score was observed. The median weight gain was 5.80g/kg/day and there was a sign increase in mean WFA z-score of 0.48 (±1.10; P <0.001)). Weight gain was similar to that of healthy infants of the same age group.	• **9 out of 10** critically ill infants achieve weight gain with Infatrini • Weight gain achieved with Infatrini in critically ill infants **matches that of healthy infants**

INFATRINI CLAIMS - NUTRITIONAL INTAKE

This study includes children with congenital heart disease (CHD)

	RESULTS	'HUMANIZED' CLAIMS
Clarke et al., J Hum Nutr Diet 2007	The INF group received 42% more protein and 15-40% more micronutrients.	• Infants receiving Infatrini consumed **85% more protein** than those receiving energy supplemented infant formula • Infants receiving Infatrini consumed **1,7g protein /kg /day more** than those receiving energy supplemented infant formula
van Waardenburg et al., Clin Nutr 2009	Protein intakes (g/kg/day) Infatrini group: 2.8 +/- 0.3 vs Energy supplemented formula: 1.5 +/- 0.1	• Infatrini provides **87% more protein** than energy supplemented formula • Energy supplemented infant formula provide approx**. 53% of the protein** provided by Infatrini
de Betue et al., Arch Dis Child 2011	Whole body protein balance was sign higher with infatrini than with std IF, resulting from sign increased protein synthesis, despite sign increased protein breakdown. First pass splanchnic Phe extraction was not sign different between the two groups. The 24 h N balance on day 5 was significantly higher in the infatrini group. The sums of plasma BCAA and EAA were also higher in the infatrini group.	• Infatrini promotes an improved whole protein balance compared to standard infant milk formula • Infatrini promotes a positive nitrogen balance through increased protein synthesis
Zhang et al., Nurs Crit Care 2018	Enteral energy intake in the INF group was sign higher than in the Std IF group from d 3. In our study, the intervention group was given 51–89 kcal/kg/day during the intervention period compared with 44–56 kcal/kg/day given to the control group	• **~ 40% higher energy intakes** with Infatrini compared to standard infant feeds • Energy intake from infatrini was **up to double** compared to standard infant feeds • Energy intakes **up to 100% higher with Infatrini** compared to standard infant feeds

INFATRINI CLAIMS - TOLERANCE & COST



	RESULTS	REFINED CLAIMS
Eveleens et al. J Hum Nutr Diet 2019	**Single arm study**: Infatrini Infatrini was generally well tolerated. The formula was stopped in 8 (11%) of the infants because of signs of feeding intolerance.	• Infatrini was well tolerated in **~90%** of critically ill infants



	RESULTS	REFINED CLAIMS
Marino et al., e-SPEN Journal 2013	**Test group**: Infatrini RTF **Control group**: Energy supplemented Std powdered IF The cost of giving RTU Infatrini to an undernourished infants was 12.51 euro/day, which was lower than the total costs of giving energy supplemented formula (16,52-19.61 euro/day).	• The total cost of providing a RTF* Infatrini is **2/3 (two- thirds) of the total cost** of providing energy supplemented infant formula • Providing a RTF* Infatrini can **save 1/3 of the total cost** compared to providing an energy supplemented infant formula • Providing an energy supplemented infant formula is **57% more costly** than providing RTF Infatrini

*ready to feed

INFATRINI CLAIMS - LENGTH OF STAY & ANTIBIOTIC USE

This study includes children with congenital heart disease (CHD)

	RESULTS	REFINED CLAIMS
Sheeffer et al., JPEN 2019	**Test group**: Infatrini **Control group**: Std IF Patients were discharged in a mean of 14 days in the intervention group and 20 days in the control group, and this difference had a borderline significance* (p = 0.057).	• Infants receiving Infatrini were discharged on average ***6 days earlier*** than those receiving energy supplemented infant formula (p = 0.057) ^ • Those receiving energy supplemented infant formula remained in ***ICU 43% longer*** than those receiving Infatrini (p = 0.057) ^ • Those receiving Infatrini remained in ***ICU for 30% shorter time*** than those receiving standard energy supplemented infant formula (p = 0.057) ^

	RESULTS	REFINED CLAIMS
Marino et al., e-SPEN Journal 2013	**Test group**: Infatrini RTF **Control group**: Energy supplemented Std powdered IF Antibiotic use was less frequent in the intervention group, in which 16 children received antibiotics compared with 24 children in the control group (p = 0.047).	• Infants receiving Infatrini had ***30% less antibiotic use*** compared to those receiving a standard infant formula (p = 0.047) ^ • Infants receiving a standard infant formula had ***50% more antibiotic use*** compared to those receiving Infatrini (p = 0.047) ^

* Authors noted “borderline significance”

^ secondary endpoint)

FALTERING GROWTH

tube/ons
infant

Infatrini Peptisorb



INTERNAL USE ONLY

Infatrini Peptisorb OUTCOMES

OUTCOMES RELATED TO **GROWTH**



OUTCOMES RELATED TO **NUTRITIONAL INTAKE**



OUTCOMES RELATED TO **TOLERANCE**



INFATRINI PEPTISORB - GROWTH

This study includes children with congenital heart disease (CHD)

	RESULTS	REFINED CLAIMS
Smith et al., Clin Nutr 2018	**Single arm study**: Infatrini Peptisorb Significant increase in weight, length, head circumference, WFL z-score and WFA z-score. 61% (n = 11) of the infants showed signs of increased growth velocity. Eleven (61%) of the infants showed signs of an increased velocity in growth between day 1 and day 28 (as confirmed by investigator consensus). Z score data showed that 6 of these 11 infants had a positive increase of nearly (n = 1) or more than 0.67 (n = 5) indicating that at the end of the study their weight was on the centile line above the one they were following at baseline. Comparison of Z scores from the historical control period 4 weeks before the study started (-2.36 ± 1.58 (n = 12)) with the Z scores from day 1 of the study (-2.67 ± 1.10 (n = 18)) show that these infants were losing weight and not growing in the 4 weeks prior to starting the trial, as they were moving further away from the 50th centile. The Z scores whilst on the trial improved and moved significantly in the right direction (baseline: -2.67 ± 1.10 (n = 18) and day 28: -2.37 ± 1.25 (n = 18), $p < 0.05$) and could be considered to show an increased growth velocity. Additionally, rates of growth from the historical control period were 13.22 ± 7.21 g per day whilst during the trial these increased to 24.59 ± 9.74 g per day (p = 0.007)	• More than ***6 out of 10 complex patients*** unable to tolerate an intact protein feed increased their growth velocity with Infatrini Peptisorb within 4 weeks • ***One third*** of complex patients achieve catch-up growth within 4 weeks with Infatrini Peptisorb • ***One third*** of complex patients gained one centile in weight in 4 weeks with Infatrini Peptisorb • Demonstrated to increase weight in complex patients unable to manage a whole protein feed.
Marino et al., J Hum Nutr Diet 2019	**Single arm study**: Infatrini Peptisorb There was a positive change in WFA z-score during PICU stay in infants who were weighed during the study period (n=17).	• Weight for age positively changed in ***all PICU infants*** receiving Infatrini Peptisorb

INFATRINI PEPTISORB CLAIMS - TOLERANCE & NUTRITIONAL INTAKE

This study includes children with congenital heart disease (CHD)

	RESULTS	REFINED CLAIMS
Smith et al., Clin Nutr 2018	**Single arm study**: Infatrini Peptisorb GI tolerance to Infatrini Peptisorb was good and either improved or remained stable over the study. 50% of parents/carers agreed that tolerance was better than on previous feed (and 44% felt there was no difference). Compliance was very high (94.0% ±12.6).	• ***94% compliance*** in infants on Infatrini Peptisorb who were previously unable to tolerate intact protein feeds
Marino et al., J Hum Nutr Diet 2019	**Single arm study**: Infatrini Peptisorb Feeding was withheld because of feeding intolerance in 1 infant (4%) on 2 occasions in PICU-1 for 2.5 h and in 2 infants (7%) on 2 occasions in PICU-2 for 19.5 h. Mean GRVs were 3.5ml/kg in PICU-1 and 16.9ml/kg in PICU-2.	• ***~95%*** of infants in PICU on Infatrini Peptisorb were able to maintain continuous feeding, without interruption

	RESULTS	REFINED CLAIMS
Smith et al., Clin Nutr 2018	**Single arm study**: Infatrini Peptisorb Total energy intake improved (+23 ± 42 kcal/kg, p = 0.037) Energy intake per kg body weight (+23 ± 42 kcal/kg, p = 0.037).	• Infatrini Peptisorb ***increased energy intake by 30%*** in complex infants unable to tolerate whole protein feeds (p = 0.037) • Infatrini Peptisorb ***increased nutritional intake / energy intake by 1 third*** in complex infants unable to tolerate whole protein feeds (p = 0.037)

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Infatrini & Infatrini Peptisorb ABSTRACTS

INTERNAL USE ONLY

CLARKE SE, EVANS S, MACDONALD A ET AL.

RANDOMISED COMPARISON OF A NUTRIENT-DENSE FORMULA WITH AN ENERGY-SUPPLEMENTED FORMULA FOR INFANTS WITH FALTERING GROWTH.

J HUM NUTR DIET 2007; 20: 329-39.

INTRODUCTION

The practice of supplementing standard infant formula with energy for infants with faltering growth has been widespread. This increases energy density but disturbs the protein : energy ratio and increases risks of microbial contamination and errors in feed preparation. This study aimed to compare the effectiveness of a nutrient-dense formula (NDF) with an energy-supplemented formula (ESF) in infants with faltering growth.

METHODS

In an open, parallel, randomized study, 49 infants with faltering growth were randomized to receive a NDF (4.2 kJ mL(-1)) or an ESF (4.2 kJ mL(-1)), for 6 weeks. Anthropometry, biochemistry, feed intake, stool and vomit frequency were collected.

RESULTS

No significant differences in tolerance, feed volumes or energy intakes were recorded but the NDF group received 42% more protein and 15-40% more vitamins and minerals. Blood urea concentration in the ESF group fell by 50% over the trial period, suggesting a suboptimal protein : energy ratio in the ESF feed. The NDF group retained a normal mean blood urea concentration, a higher urinary potassium concentration and did not have the significant fall in length z-score seen in the ESF group.

CONCLUSION

Increasing the energy content of normal infant formula without also increasing protein and micronutrients should not be practiced in infants with faltering growth.

Link to Full Paper

MARINO LV, MEYER R, COOKE ML.

COST COMPARISON BETWEEN POWDERED VERSUS ENERGY DENSE INFANT FORMULA FOR UNDERNOURISHED CHILDREN IN A HOSPITAL SETTING.

E-SPEN JOURNAL 2013; 8: E145 - E149.

BACKGROUND & AIMS

Ready to use (RTU) infant formulas became available for use in South African hospitals in 2005. However, a major barrier to use these formulae has been the perceived high product cost compared to the product cost of powdered infant formula (PIF). The aim of this cost comparative analysis was to determine the entire cost of these two feeding models.

METHODS

This retrospective cost analysis used patient data generated from the Red Cross War Memorial Children Hospital (RCWMH), Cape Town, South Africa from 2007 to 2008. The annual cost of administering an energy dense RTU infant feed was compared to a fortified PIF, using published data of undernutrition at 34%. Only direct costs associated with the preparation and delivery were included in the analysis.

RESULTS

The fortified PIF versus RTU for 1 day per undernourished child cost 16.52 Euros and 19.61 Euros for the enriched PIF with sunflower and MCT oil respectively, versus the cost of the energy dense RTU feed of 12.51 Euros per day.

CONCLUSIONS

The decision to feed undernourished infants with enriched PIF versus energy dense RTU feed should not be based not only on the cost of the product, but also the hidden costs, as shown by this publication.

Link to Full Paper

VAN WAARDENBURG DA, DE BETUE CT VAN GOUDOEVER JB ET AL.

CRITICALLY ILL INFANTS BENEFIT FROM EARLY ADMINISTRATION OF PROTEIN AND ENERGY-ENRICHED FORMULA; A RANDOMIZED CONTROLLED TRIAL.

CLIN NUTR 2009; 28: 249-55.

BACKGROUND & AIMS

Nutritional support improves outcome in critically ill infants but is impeded by fluid restriction, gastric intolerance and feeding interruptions. Protein and energy-enriched infant formulas may help to achieve nutritional targets earlier during admission and promote anabolism.

METHODS

Randomized controlled design. Infants with respiratory failure due to RSV-bronchiolitis received a protein and energy-enriched formula (PE-formula, n = 8) or a standard formula (S-formula, n = 10) during 5 days after admission. Primary outcome: nutrient delivery, energy and nitrogen balance and plasma amino acid concentrations. Secondary outcome: tolerance and safety.

RESULTS

Nutrient intakes were higher in PE fed infants and met population reference intake (PRI) on day 3-5 whilst in S-fed infants PRI was met on day 5 only. Cumulative nitrogen balance (cNB) and energy balance (cEB) were higher in PE-infants compared to S-infants (cNB: 866 +/- 113 vs. 296 +/- 71 mg/kg; cEB: 151 +/- 31 and 26 +/- 17 kcal/kg, both $P < 0.01$). Essential amino acid levels were higher in PE-infants but within reference limits whereas below these limits in S-infants. Both formulas were well tolerated.

CONCLUSIONS

Early administration of a protein and energy-enriched formula in critically ill infants is well tolerated, promotes a more adequate nutrient intake and improves energy and nitrogen balance without adverse effects.

Link to Full Paper

DE BETUE CT, VAN WAARDENBURG DA, DEUTZ NE ET AL.

INCREASED PROTEIN-ENERGY INTAKE PROMOTES ANABOLISM IN CRITICALLY ILL INFANTS WITH VIRAL BRONCHIOLITIS: A DOUBLE-BLIND RANDOMISED CONTROLLED TRIAL.

ARCH DIS CHILD 2011; 96: 817-822.

OBJECTIVE

The preservation of nutritional status and growth is an important aim in critically ill infants, but difficult to achieve due to the metabolic stress response and inadequate nutritional intake, leading to negative protein balance. This study investigated whether increasing protein and energy intakes can promote anabolism. The primary outcome was whole body protein balance, and the secondary outcome was first pass splanchnic phenylalanine extraction (SPE(Phe)).

DESIGN

This was a double-blind randomised controlled trial. Infants (n=18) admitted to the paediatric intensive care unit with respiratory failure due to viral bronchiolitis were randomised to continuous enteral feeding with protein and energy enriched formula (PE-formula) (n=8; 3.1±0.3 g protein/kg/24 h, 119±25 kcal/kg/24 h) or standard formula (S-formula) (n=10; 1.7±0.2 g protein/kg/24 h, 84±15 kcal/kg/24 h; equivalent to recommended intakes for healthy infants <6 months). A combined intravenous-enteral phenylalanine stable isotope protocol was used on day 5 after admission to determine whole body protein metabolism and SPE(Phe).

RESULTS

Protein balance was significantly higher with PE-formula than with S-formula (PE-formula: 0.73±0.5 vs S-formula: 0.02±0.6 g/kg/24 h) resulting from significantly increased protein synthesis (PE-formula: 9.6±4.4, S-formula: 5.2±2.3 g/kg/24 h), despite significantly increased protein breakdown (PE-formula: 8.9±4.3, S-formula: 5.2±2.6 g/kg/24 h). SPE(Phe) was not statistically different between the two groups (PE-formula: 39.8±18.3%, S-formula: 52.4±13.6%).

CONCLUSIONS

Increasing protein and energy intakes promotes protein anabolism in critically ill infants in the first days after admission. Since this is an important target of nutritional support, increased protein and energy intakes should be preferred above standard intakes in these infants.

Link to Full Paper

ZHANG H, GU Y, MI Y ET AL.

HIGH-ENERGY NUTRITION IN PAEDIATRIC CARDIAC CRITICAL CARE PATIENTS: A RANDOMIZED CONTROLLED TRIAL.

NURS CRIT CARE 2018, DEC 9. [EPUB AHEAD OF PRINT]

BACKGROUND

Previous studies have shown that feeding a high-energy formula (HF) to infants after cardiac surgery increases energy intake, with fewer side effects on cardiopulmonary function. However, impacts on weight gain and gastrointestinal function remain unclear.

AIMS AND OBJECTIVES

To determine the impact of HF compared with standard formula on weight gain and gastrointestinal tolerance in postoperative infants with congenital heart disease.

DESIGN

This was a randomized controlled trial.

METHODS

The setting of the study was at a 20-bed cardiac intensive care unit at a tertiary children's hospital in China. Study population included infants <1 year of age who underwent cardiac surgery and were allocated to the intervention group (n =32) or control group (n =32). The intervention group received HF (100 kcal/100 mL), and the control group received standard formula (67 kcal/100 mL) for 7 days during the stabilized postoperative period at the cardiac intensive care unit. Primary outcomes were weight gain and gastrointestinal intolerance. Secondary outcomes were energy intake and standard intensive care characteristics

RESULTS

Infants who received HF (n =30) showed less weight loss than those who received standard formula (n =29); −16 g [95% confidence interval (CI): −74 to 42] versus −181 g (95% CI: −264 to −99), P =0·001. The evaluation of gastrointestinal intolerance showed that the intervention group had several side effects, such as abdominal distension (n =1), gastric retention (n =2) and diarrhoea (n =1), while the control group had no problems. Enteral energy intake in the intervention group was higher than the control group from day three

CONCLUSION

Infants after cardiac surgery fed with HF gained more weight but had increased feeding intolerance. However, the feeding intolerance symptoms could be relieved by medication and did not affect feeding advancement.

RELEVANCE TO CLINICAL PRACTICE

Paediatric intensive care clinicians should consider gradually increasing the energy density of the formula during feeding and assess feeding intolerance signs in some children with malnutrition after cardiac surgery.

Link to Full Paper

SCHEEFFER VA, RICACHINEVSKY CP, FREITAS AT, SALAMON F, RODRIGUES FFN, BRONDANI TG ET AL.

TOLERABILITY AND EFFECTS OF THE USE OF ENERGY-ENRICHED INFANT FORMULA AFTER CONGENITAL HEART SURGERY: A RANDOMIZED CONTROLLED TRIAL.

JPEN 2019 MAR 22. [EPUB AHEAD OF PRINT].

BACKGROUND

Undernutrition is a common problem among children with congenital heart disease (CHD) and may lead to poorer surgical outcomes. A higher intake of energy during the postoperative period of CHD surgery seems to be associated with better outcomes. This study aimed to investigate the effect of the use of energy-enriched formula (EE-formula) compared with normocaloric formula during 30 days after CHD surgery.

METHODS

A randomized controlled trial with patients undergoing heart surgery in a tertiary hospital in southern Brazil from March 2017 to December 2017 was performed. The intervention group received EE-formula (1 kcal/mL), and the control group received normocaloric formula (0.67 kcal/mL). The researcher in charge of anthropometric evaluation was blinded to the randomization.

RESULTS

Fifty-nine patients were included; 30 in control group and 29 in intervention group. There were no statistically significant differences between groups regarding age, gender, anthropometry, and surgical risk classification after randomization. A statistically significant difference in z-score of weight for age and in weight gain variation rate between groups after intervention was observed. Antibiotic use was less frequent in the intervention group, and hospital length of stay was shorter. General gastrointestinal side effects were similar between groups, whereas diarrhea was more frequent in the intervention group. However, this side effect was limited and had spontaneous resolution in 4 out of 6 cases.

CONCLUSION

This study demonstrates that EE-formula use after heart surgery of patients with CHD is well tolerated and may improve short-term nutrition outcome, decrease hospital stay, and reduce antibiotic use.

Link to Full Paper

EVELEENS RD, DUNGEN DK, VERBRUGGEN SCAT ET AL.

WEIGHT IMPROVEMENT WITH THE USE OF PROTEIN AND ENERGY ENRICHED NUTRITIONAL FORMULA IN INFANTS WITH A PROLONGED PICU STAY.

J HUM NUTR DIET 2019; 32: 3-10.

BACKGROUND

Reaching an optimal nutritional intake is challenging in critically ill infants. One possible way to minimise nutritional deficits is the use of protein and energy-enriched (PE)-formulas. We aimed to describe weight achievement and gastrointestinal symptoms in infants admitted to the paediatric intensive care unit (PICU) while receiving PE-formula for a prolonged period.

METHODS

Records from infants admitted to a multidisciplinary PICU and using PE-formula were analysed retrospectively. Infants were eligible if they received PE-formula daily for at least 2 weeks. Weight achievement was determined as the difference between weight-for-age (WFA) Z-scores at the start and end of PE-formula use. Gastrointestinal symptoms, including gastric residual volume, constipation and vomiting, were evaluated as tolerance parameters.

RESULTS

Seventy infants with a median [interquartile range (IQR)] age of 76 (30–182) days were eligible. The PICU duration was 50 (35–83) days during which they received PE-formula for 30 (21–54) days. Predominant admission diagnoses were post-cardiac surgery, respiratory and cardiac diagnosis. A significant mean (SD) WFA Z-score increase of 0.48 (1.10) ($P < 0.001$) and a median (IQR) weight gain of 5.80 (3.28–9.04) g kg^{-1} day^{-1} was observed. Multivariate regression showed that a lower WFA Z-score at start was associated with a higher WFA Z-score increase during PE-formula use (β -0.35 (95% confidence interval = -0.50 to -0.19); $P < 0.001$). The maximum 24-h gastric residual volume was 8.1 mL (IQR = 2.2–14.3) for each 1 kg in bodyweight. Three (4%) infants were treated for diarrhoea and three infants were treated for vomiting

CONCLUSIONS

The majority of infants with a prolonged PICU stay showed weight improvement when using PE-formula. PE-formula was well tolerated because gastrointestinal symptoms only occurred in few infants.

Link to Full Paper

SMITH C, McCABE H, MACDONALD S ET AL.

IMPROVED GROWTH, TOLERANCE AND INTAKE WITH AN EXTENSIVELY HYDROLYSED PEPTIDE FEED IN INFANTS WITH COMPLEX DISEASE.

CLIN NUTR 2018; 37: 1005-1012.

BACKGROUND & AIMS

Infants with complex medical conditions often display faltering growth due to elevated nutritional requirements, poor intake and intolerance of feeding with malabsorption and maldigestion. As a result their nutritional management can be extremely challenging and enteral nutritional support is required. This study aimed to investigate the effectiveness, tolerance and acceptability of nutritional support with a specially formulated, paediatric peptide feed in infants with complex disease and signs of growth faltering with their current nutritional management.

METHODS

This prospective intervention study investigated gastrointestinal (GI) tolerance, nutritional intake and compliance with feeding, anthropometry and growth in 18 infants (mean age 6.11 months ± 4.69, mean weight 4.97 kg ± 1.71) during 28 days of enteral nutritional support with a paediatric (1 kcal/ml) readymade peptide feed.

RESULTS

GI tolerance to nutritional support with a peptide enteral feed was good and either improved or remained stable over the study. Compliance was excellent (94.0% ± 12.6), total energy intake improved (þ23 ± 42 kcal/kg, p ¼ 0.037) and mean weight (0.61 kg ± 0.31, p ¼ 0.0001), length (1.89 ± 1.77 cm, p ¼ 0.0001), head circumference (1.33 ± 1.29 cm, p ¼ 0.001), weight for length Z score ($p < 0.05$), and weight for age Z score ($p < 0.05$) significantly improved. Sixty one percent (n ¼ 11) of the infants showed signs of increased growth velocity, moving upwards in terms of their centiles. All 18 infants continued with the paediatric, peptide enteral feed once the study was complete.

CONCLUSIONS

This prospective study showed that nutrition support with a specially formulated, paediatric peptide readymade feed was well tolerated, helped to promote growth, and can be considered suitable for use in infants with complex disease and faltering growth who are unable to tolerate a whole protein feed.

Link to Full Paper

MARINO LV, EVELEENS RD, MORTON K, VERBRUGGEN SCAT, JOOSTEN KFM.

PEPTIDE NUTRIENT-ENERGY DENSE ENTERAL FEEDING IN CRITICALLY ILL INFANTS: AN OBSERVATIONAL STUDY.

J HUM NUTR DIET 2019 MAR 8. [EPUB AHEAD OF PRINT]

BACKGROUND

Enteral feeding is challenging in critically ill infants. Target intakes are often not achieved as a result of fluid restriction, procedural interruptions and perceived enteral feeding intolerance. In those infants perceived to have poor feeding tolerance, the use of a peptide nutrient-energy dense enteral feed (PEF) may improve nutritional intake and minimise feeding interruptions as a result of gastrointestinal symptoms. The aim of this observational study was to characterise the use of a PEF amongst critically ill infants in two paediatric intensive care units (PICUs).

METHODS

Records from critically ill infants aged <12 months admitted to two PICUs were retrospectively reviewed with a PICU length of stay (LOS) ≥ 7 days. Achievement of nutritional targets for the duration of PEF was reviewed. Gastrointestinal symptoms, including gastric residual volume, constipation and vomiting, were evaluated as tolerance parameters

RESULTS

In total, 53 infants were included, with a median age on admission of 2.6 months. Median admission weight was 3.9 kg in PICU-1 and 4.7 kg in PICU-2. Median (interquattile range) energy intake in PICU-1 and PICU-2 was 68 (47–92) and 90 (63–124) kcal kg^{-1}, respectively, and median (interquartile range) protein intake 1.7 (1.1–2.4) g kg^{-1} and 2.5 (1.6–3.2) g kg^{-1}, respectively. Feeding was withheld because of feeding intolerance in one infant (4%) on two occasions in PICU-1 for 2.5 h and in two infants (7%) on two occasions in PICU-2 for 19.5 h. Gastric residual mean (SD) volumes were 3.5 (5.4) mL kg^{-1} in PICU-1 and 16.9 (15.6) mL kg^{-1} in PICU-2.

CONCLUSIONS

Peptide nutrient-energy dense feeding in infants admitted to the PICU is feasible, well tolerated and nutritional targets are met. However, with this study design, it is not possible to draw any conclusions regarding the benefit of PEF over standard PE feed in critically ill children and future work is required to clarify this further.

Link to Full Paper

INTERNAL USE ONLY

FALTERING GROWTH
HCP DRIVEN

ons kids



FALTERING GROWTH

ons
kids



FALTERING GROWTH

(HCP driven)

ons kids - Fortini / Nutrinidrink



FORTINI/NUTRINIDRINK SMOOTHIE
RTD 1.5KCAL/ML
WITH FIBRE



FORTINI/NUTRINIDRINK COMPACT
RTD 2.4KCAL/ML
WITH FIBRE



FORTINI/NUTRINIDRINK
1.5KCAL/ML RTD
WITH/WITHOUT FIBRE



FORTINI/NUTRINIDRINK
1.0 KCAL/ML RTD
WITH FIBRE



FORTINI/NUTRINI CREAMY FRUIT
RTD 1.5KCAL/ML
WITH FIBRE



FORTINI/NUTRINIDRINK 1.5KCAL/ML
POWDER
WITHOUT FIBRE



FORTINI CHINA
1.0KCAL/ML POWDER
WITH scGOS/lcFOS

FORTINI RANGE – EVIDENCE OVERVIEW



FALTERING GROWTH

ons
kids

Fortini / Nutrinidrink MF 1.0 & 1.5 kcal/ml



INTERNAL USE ONLY

Fortini / Nutrinidrink MF OUTCOMES

OUTCOMES RELATED TO **GROWTH**





OUTCOMES RELATED TO **APPETITE**

OUTCOMES RELATED TO **NUTRITIONAL INTAKE**





OUTCOMES RELATED TO **TOLERANCE**

OUTCOMES RELATED TO **COMPLIANCE**





OUTCOMES RELATED TO **ACCEPTABILITY**

FORTINI / NUTRINIDRINK MF* CLAIMS - GROWTH & APPETITE



	RESULTS	REFINED CLAIMS
Devaera et al., PGHN 2018*	Test group: Fortini/Nutrinidrink MF 1.5 kcal/ml Control group: Fortini/Nutrinidrink MF 1.0 kcal/ml No significant differences between the two groups in total weight gain over the 4-week intervention period, daily weight gain, and the % of children who reached a WHZ score of >−1 (Table 3). Total increase in body weight (kg) (1.5 kcal) 0.42±0.40 (1.0kcal) 0.49±0.49 p-value=0.43 About one-third of the children in both groups achieved a WHZ >−1. These children had a higher initial WHZ than those who still had a WHZ <−1 after the 4-week intervention period. Children with milder forms of undernutrition can achieve catch up in weight in around 2 weeks of intervention.	Fortini/NutriniDrink MF 1.0 & 1.5 kcal/ml: - Shows **catch up growth in 28 days** in malnourished children (p = 0.43) ^ - Shows **catch up growth in 14 days** in children with milder forms of malnutrition (p = 0.43) ^



	RESULTS	REFINED CLAIMS
Devaera et al., PGHN 2018*	Test group: Fortini/Nutrinidrink MF 1.5 kcal/ml Control group: Fortini/Nutrinidrink MF 1.0 kcal/ml There were no significant differences in total energy intake from food consumed between the two groups, both at baseline and day 28. Slightly lower energy intake from solid food after the intervention (−67.62±362.24 kcal in the intervention group and −100.88±391.58 kcal in control group) but this was not significantly different (p=0.67) children with milder forms of undernutrition can achieve catch up in weight in around 2 weeks of intervention. **Analysis of total energy intake at day 28, did not show displacement of solid food by these ONS.**	Fortini/NutriniDrink MF 1.0 & 1.5 kcal/ml: Fortini/NutriniDrink MF **does not impact the intake of everyday foods.** (p = 0.67) ^

*Fortini/Nutrinidrink MF 1.5 and 1.0 kcal/ml

^ secondary endpoint)

FORTINI / NUTRINIDRINK MF* CLAIMS – NUTRITIONAL INTAKE



	RESULTS	REFINED CLAIMS
Devaera et al., PGHN 2018*	**Test group**: Fortini/Nutrinidrink MF 1.5 kcal/ml **Control group**: Fortini/Nutrinidrink MF 1.0 kcal/ml There were no significant differences in total energy intake from food consumed between the two groups, both at baseline and day 28. Slightly lower energy intake from solid food after the intervention (−67.62±362.24 kcal in the intervention group and −100.88±391.58 kcal in control group) but this was not significantly different (p=0.67) Analysis of total energy intake at day 28, did not show displacement of solid food by these ONS.	Fortini/NutriniDrink MF **does not impact the intake of everyday foods** (p = 0.67) ^
Daly et al. J Hum Nutr Diet 2004	**Test group:** Fortini/Nutrinidrink MF. **Control group**: control feeds without fibre. The fibre intake was significantly higher in the test group ($p < 0.0001$). **In the test group, the median intake of fibre was 8 - 10 g per day, with the trial supplement providing approximately 50% of this**. The median intake of fibre in the control group was 3-4g day.	• Fortini/NutriniDrink MF provides **50% of the daily fibre** intake ($p < 0.0001$) • Fortini/NutriniDrink MF supports **double the daily fibre** intake compared to the non-fiber equivalent ($P < 0.0001$)
Başaran et al. Surg Med. 2020	**Single-arm study:** Fortini/Nutrinidrink MF 1.5 kcal/ml • reduction in the number of patients with excessive or insufficient amounts of ferritin, B12 and vitamin D concentrations with 80%, 41.7% and 39.3% respectively over six months. • Improvement of ferritin, b12 and vitamin D micronutrients after six months of supplementation.	• Fortini/NutriniDrink MF 1.5 kcal/ml **improves micronutrient levels after 6 months** in malnourished children • Fortini/NutriniDrink MF **improves Vitamin D and ferritin levels after 6 months** in malnourished children
Silistre et al. J Surg Med. 2020	**Single-arm study**: Fortini/Nutrinidrink MF 1.5 kcal/ml Mean iron concentrations of iron deficient patients increased from 36.6 (11.67) ug/dL to 46.5 (19.41) ug/dL and 57.3 (26.48) ug/dL at the 3rd and the 6th month of treatment, respectively, thus reducing the number of iron deficient patients from 27 (61.4%) to 22 (50%) and 16 (36.3%)	• Fortini/NutriniDrink MF 1.5 kcal/ml **improves iron levels** in malnourished children* and reduces the number of iron deficient patients. **with a history of febrile seizure*

*Fortini/Nutrinidrink MF 1.5 and 1.0 kcal/ml

FORTINI / NUTRINIDRINK MF* CLAIMS – TOLERANCE



	RESULTS	REFINED CLAIMS
Devaera et al., PGHN 2018*	Testgroup: Fortini/Nutrinidrink MF 1.5 kcal/ml Control group: Fortini/Nutrinidrink MF 1.0 kcal/ml No significant differences between the groups in terms of stool consistency and gastrointestinal symptoms. Stool frequency and consistency during the study were acceptable, with most children having one bowel movement per day with normal consistency.	• Fortini/NutriniDrink MF 1.0 & 1.5 kcal is **well tolerated** in malnourished children
Daly et al. J Hum Nutr Diet 2004	Test group: Fortini/Nutrinidrink MF 1.5 kcal/ml. Control group: control feeds without fibre. Population: chronically ill children with poor weight gain With Fortini MF no abdominal symptoms such as flatulence, bloating, abdominal distension was reported. laxative usage was reduced: 5 out of 7 children who took daily laxatives at the beginning of the trial, reduced laxative dosage. No differences were reported in the frequency or consistency of stools in either group.	• Fortini/NutriniDrink MF 1.5 kcal/ml is **well tolerated** in chronically ill children with poor weight gain • Fortini/NutriniDrink MF 1.5 kcal/ml **reduced the use of laxatives** in 5/7 chronically ill children with poor weight gain
Silistre et al. J Surg Med. 2020	Single-arm study: Fortini/Nutrinidrink MF 1.5 kcal/ml The product was well-tolerated among the majority of patients (72.9%, n=35). Six patients (12.5%) had distension, 3 patients vomited (6.3%), and 4 patients (8.3%) had not tolerated the nutritional intervention at the 6th month after the initial intervention	• Fortini/NutriniDrink MF 1.5 kcal/ml is **well tolerated** in malnourished children* **with a history of febrile seizure*

*Fortini/Nutrinidrink 1.5 kcal/ml

FORTINI / NUTRINIDRINK MF* CLAIMS – COMPLIANCE & ACCEPTABILITY



	RESULTS	REFINED CLAIMS
Devaera et al., PGHN 2018*	Test group: Fortini/Nutrinidrink MF 1.5 kcal/ml Control group: Fortini/Nutrinidrink MF 1.0 kcal/ml Similar compliance in both groups, with a product intake of 80±24% and 81±22% of prescribed volume in the 1.5 kcal/mL and 1.0 kcal/mL groups respectively (p=0.79).	• **>80%** of the children were compliant with Fortini/Nutrinidrink MF 1.0 and 1.5 kcal/ml • **> 80%** of the children took the prescribed volume of Fortini/Nutrinidrink MF 1.0 and 1.5 kcal/ml • **>8 out of 10** children are compliant with Fortini/Nutrinidrink MF 1.0 and 1.5 kcal/ml



	RESULTS	REFINED CLAIMS
Devaera et al., PGHN 2018*	Test group: Fortini/Nutrinidrink MF 1.5 kcal/ml Control group: Fortini/Nutrinidrink MF 1.0 kcal/ml Both sip feeds were equally well appreciated; only 8 (16.7%) children in the intervention group and 7 children in the control group (14.0%) did not like the sip feeds (p=0.71).	• > **85%** of malnourished children liked Fortini/Nutrinidrink MF 1.0 and 1.5 kcal/ml

*Fortini/Nutrinidrink MF 1.5 and 1.0 kcal/ml

FALTERING GROWTH

ons
kids

Fortini / Nutrinidrink Compact MF



INTERNAL USE ONLY

Fortini / Nutrinidrink Compact MF OUTCOMES

OUTCOMES RELATED TO **GROWTH**





OUTCOMES RELATED TO **APPETITE**

OUTCOMES RELATED TO **NUTRITIONAL INTAKE**





OUTCOMES RELATED TO **TOLERANCE**

OUTCOMES RELATED TO **COMPLIANCE**





OUTCOMES RELATED TO **ACCEPTABILITY**

FORTINI / NUTRINIDRINK COMPACT MF CLAIMS - GROWTH & TOLERANCE



	RESULTS	REFINED CLAIMS
Hubbard et al. 2020	Test group: Fortini/Nutrinidrink Compact MF (2,4kcal/mL) [cONS] Control group: Standard ONS (1,5kcal/mL) - Fortini (MF) & Pediasure Plus[sONS] Increases in weight (p=0,007), height (p<0,001) and height z-score(p = 0.006) were observed over time with the cONS, which were not apparent with the sONS	With **Fortini/Nutrinidrink Compact:** • Significant weight (p=0,007) & height (p<0,001) growth demonstrated in just 28 days • Catch up growth achieved in just 28 days • Height *z*-score significantly increased vs standard ONS group in just 28 days (p = 0.006)



	RESULTS	REFINED CLAIMS
Hubbard et al. 2020	The number of patients reporting GI symptoms was low in both groups with no significant changes over time within groups.	• Fortini/NutriniDrink Compact ONS **was well tolerated** across a number of complex conditions*

*Primary diagnosis: FG with underlying conditions including respiratory (n = 11), genetic (n = 7), central nervous system (n = 7), gastro-intestinal(n = 5), cardiac (n = 4), neurodevelopmental (n = 4),prematurity (n = 3), intrauterine growth retardation (n = 2), developmental delay (n = 1), and autoimmune (n = 1) conditions.

FORTINI / NUTRINIDRINK COMPACT MF CLAIMS – NUTRITIONAL INTAKE & APPETITE



	RESULTS	REFINED CLAIMS
Hubbard et al. 2020	Test group: Fortini/Nutrinidrink Compact MF (2,4kcal/mL) [cONS] Control group: Standard ONS (1,5kcal/mL) - Fortini (MF) & Pediasure Plus[sONS] **Mean total daily energy intake from diet and ONS was significantly higher** at day 28 with the cONS (**1707 kcal/day**, 95% CI:1458, 1956) versus the sONS (**1176 kcal/day**, 95%CI 889, 1453), a difference of + 531 kcal/day (PP****: p = 0.059 adjusted for baseline energy intake & age). **Mean daily energy intake from diet alone** was significantly greater with the cONS compared with the sONS at day 28 (p = 0.017 unadjusted, p = 0.159 adjusted for baseline energy intake) but did not change significantly over time in either group. **Mean total daily protein intake from diet and ONS was significantly higher** at day 28 with the cONS **(54.1 g/day**, 95%CI 46.6, 61.7) versus the sONS **(36.0 g/day**, 95%CI 27.6,44.4), a difference of + 10.1 g/day (PP****:p = 0.011) and **increased over time with the cONS**, although there was no change with the sONS. **Mean daily protein intake from diet alone** was significantly higher with the cONS compared with the sONS at day 28 in both ITT and PP (p = 0.039 and p = 0.019 respectively, adjusted for mean baseline protein intake) ****Data are based on per protocol analysis	Fortini/Nutrinidrink Compact • **improved nutritional intake from ONS & from diet/everyday foods** in just 4 weeks (p = 0.059)* • achieved 45% **higher mean total energy vs standard ONS** in just 4 weeks **(p = 0.059)*** • supported **higher nutritional intake from diet** alone than standard ONS **(p = 0.017)**** • led to **improved intake** from diet/ everyday foods **(p = 0.017)**** Fortini/Nutrinidrink Compact • **improved protein intake from ONS & from diet/everyday foods** in just 4 weeks (p = 0.011) • achieved **50% higher mean total protein vs standard ONS** (p = 0.011) • supported **higher protein intake from diet alone** than standard ONS **(p = 0.019)** • **Protein targets achieved faster** with Fortini/Nutrinidrink Compact vs standard ONS

*borderline statistically significant
** Unadjusted P: The authors reported the intake "significantly greater"
! For calculations, please see in the notes section



	RESULTS	REFINED CLAIMS
Hubbard et al. 2020	With the cONS a significantly greater proportion of patients reported their appetite had improved over time (48%), compared with the sONS (12%, p = 0.018).	Fortini/Nutrinidrink Compact led to: • **Improved appetite (4-fold)** vs standard ONS **(p = 0.018)**. • **4 times greater appetite** vs standard ONS **(p = 0.018)**.

FORTINI / NUTRINIDRINK COMPACT MF* CLAIMS – COMPLIANCE & ACCEPTABILITY



	RESULTS	REFINED CLAIMS
Hubbard et al. 2020	Test group: Fortini/Nutrinidrink Compact MF (2,4kcal/mL) [cONS] Control group: Standard ONS (1,5kcal/mL) - Fortini (MF) & Pediasure Plus[sONS] With the cONS there were a significantly higher number of patients consuming ≥ 75% of their prescribed ONS versus those consuming less (81% vs. 19%, p = 0.005, PP), which was not apparent with the sONS (59% vs.41%, p = 0.467, PP)	• With Fortini/NutriniDrink Compact **37% more patients were compliant** vs standard ONS • **There is greater patient compliance** with Fortini/NutriniDrink Compact vs standard ONS

! For calculations, please see in the notes section



	RESULTS	REFINED CLAIMS
Hubbard et al. 2020	The cONS was well accepted with 60% finding it pleasant to drink, 65% enjoying the taste and 68% liking the thickness.	• Fortini/NutriniDrink Compact had a good acceptability rating (>60% for taste & thickness)

INTERNAL USE ONLY

Fortini / Nutrinidrink ABSTRACTS

DEVAERA Y. ET AL.

COMPARING COMPLIANCE AND EFFICACY OF ISOCALORIC ORAL NUTRITIONAL SUPPLEMENTATION USING 1.5 KCAL/ML OR 1 KCAL/ML SIP FEEDS IN MILDLY TO MODERATELY MALNOURISHED INDONESIAN CHILDREN: A RANDOMIZED CONTROLLED TRIAL.

PEDIATR GASTEROENTROL HEPATOL NUTR 2018;21(4):315-320.

PURPOSE

This study set out to evaluate the compliance to, and efficacy of oral supplementation, using a 1.5 kcal/mL or 1 kcal/mL sip feed, in children with mild to moderate malnutrition.

METHODS

This was a parallel, randomized, controlled open-label trial in children aged 3 to 6 years with a weight for height Z (WHZ) score <-1 and ≥-3, who were randomized to receive a total of 600 kcal/day from either a 1.5 kcal/mL or a 1.0 kcal/mL pediatric sip feed for 28 days. Assessments included daily study product intake, body weight, tolerance and dietary intake from solid food.

RESULTS

Of 110 children recruited, 98 (mean ± standard deviation of age 49±7 months) completed the study. Both sip feeds were well tolerated, with high compliance (80±24% and 81±22% of prescribed volume in 1.5 kcal/mL and 1.0 kcal/mL groups respectively, p=0.79). Both study groups gained similar weight during the 28 days intervention period (0.42±0.40 kg in 1.5 kcal/mL group vs. 0.49±0.49 kg in 1.0 kcal/mL group, p=0.43). There were no significant differences between the groups in weight gain and in the change in WHZ score over the intervention period. Dietary analysis at the end of the study did not show replacement of solid food by the oral nutritional supplements.

CONCLUSION

In children with mild to moderate malnutrition, both 1.5 kcal/mL and 1 kcal/mL pediatric sip feeds had high compliance and were well tolerated, and were equally effective in promoting weight gain in the 28 days study period.

Link to Full Paper

DALY A. ET AL.

IS FIBRE SUPPLEMENTATION IN PAEDIATRIC SIP FEEDS BENEFICIAL?

J HUM NUTR DIET 2004;17:365-70

SUMMARY

The usefulness of a paediatric fibre containing sip feed specifically formulated for paediatrics has not been evaluated. In an open, prospective, parallel study the efficacy, safety and tolerance of a paediatric fibre-containing sip feed designed for children weighing 8-20 kg (1-6 years) was compared with a fibre-free sip feed in 60 children with chronic illness. The subjects either received a trial sip feed containing 150 kcal (100 ml)(-1) and 2.0 g (100 ml)(-1) of fibre or a fibre-free equivalent control sip feed for 12 weeks. Blood biochemistry, haematology, anthropometry, tolerance and food intake data were estimated during week 1 and 12. The fibre intake was higher ($P < 0.0001$) and laxative usage decreased in the fibre-containing sip feed group. The sip feed provided almost 50% of fibre intake in the trial group. There were no differences in sip feed tolerance, anthropometry, nutritional biochemistry or haematology between the two groups. Sip feeds provide an important source of fibre for sick children with normal gut function requiring nutritional support.

Link to Full Paper

BAŞARAN M. ET AL.

ENTERAL FEED BASED GRADUAL IMPROVEMENT OF BODY MASS INDEX AND NORMALIZATION OF MICRONUTRIENTS IN CHILDREN WITH MALNUTRITION.

J SURG MED. 2020;4(9):826-829

AIM

Malnutrition is a serious and frequently encountered condition affecting more than 900 million individuals worldwide. Its relationship with negative clinical outcome, bad prognosis and susceptibility to diseases has been demonstrated in numerous studies alongside with the importance of early nutritional intervention. The aim of this study was to define the beneficial influence of a hypercaloric enteral supplement on body mass index (BMI) z-score as well as ferritin, vitamin B12 and vitamin D micronutrients.

METHODS

This study is a retrospective observational study. Records of patients who were diagnosed with malnutrition via a physician by having height and weight scores below -2 standard deviation were collected from Gaziosmanpaşa Training and Resource Hospital, Istanbul, Turkey. A comparative statistical analysis was performed on 205 pediatric malnutrition patients (ages 1 to 16) by gathering their BMI, ferritin, b12 and vitamin D at baseline with their measurements at 2 follow-up visits after the administration of hypercaloric (1.5kcal/mL) enteral supplement over 6 months.

RESULTS

There was a significant inverse correlation between BMI z-scores and the duration of enteral supplement administration, reflected by a 33.2% reduction of the mean BMI z-scores from -2.11 to -0.7 over 6 months ($Z=-12.4$, $P<0.001$). Additionally, there was a reduction in the number of patients with excessive or insufficient amounts of ferritin, b12 and vitamin D concentrations with 80%, 41.7% and 39.3% respectively over six months.

CONCLUSIONS

Hypercaloric enteral supplementation is a short-acting and highly beneficial nutritional intervention in pediatric patients diagnosed with malnutrition, which provides a robust improvement in the BMI z-scores as well as a 2-tailed improvement of aforementioned micronutrients after six months of supplementation.

Link to Full Paper

SILISTRE ES, ET AL.

EFFECTS OF HYPERCALORIC ENTERAL INTERVENTION ON MALNUTRITION PATIENTS WITH A HISTORY OF FEBRILE SEIZURE BEFORE THE AGE OF SIX.

J SURG MED. 2020;4(9):738-742.

AIM

Febrile seizure is the most prevalent (~5%) convulsion in children between 3 to 60 months of age and has been related to iron deficiency. Thus, when it is combined with malnutrition, it may increase negative outcomes. In this study, we present the effects of hypercaloric (1.5 kcal/mL) nutritional intervention on undernourished children with a history of febrile convulsions prior to the age of 6.

METHODS

A cohort of 44 patients between ages 1-6 years with a history of a febrile seizure was included in the study. Hypercaloric nutritional intervention was applied to all patients. Baseline patient records containing anthropometrical and micronutrient measurements were compared with the 3rd month and the 6th month visits. All patient records were retrospectively obtained from Istanbul Research and Training Hospital, İstanbul, Turkey.

RESULTS

There were significant improvements in the z-scores of weight (P=0.002) and body mass index (P<0.001). Approximately 50% of iron and 25-hydroxyvitamin D3 (25D3) deficient patients were cured and their serum concentrations increased significantly (P<0.001 for both). Treatment did not affect iron concentrations in patients without iron deficiency (P=0.074). Normal concentrations of 25D3, folate, and vitamin B12 improved inside the optimal micronutrient ranges without toxicity.

CONCLUSION

Overall, hypercaloric nutritional intervention abated iron and 25D3 deficiency and significantly improved the z-scores of BMI and weight in malnourished pediatric patients under the age of 6 with a history of febrile seizures without toxicity

Link to Full Paper

HUBBARD, GARY P., ET AL.

ENERGY-DENSE, LOW-VOLUME PAEDIATRIC ONS IMPROVE TOTAL NUTRIENT INTAKE AND INCREASE GROWTH IN PAEDIATRIC PATIENTS REQUIRING NUTRITIONAL SUPPORT: RESULTS OF A RANDOMISED CONTROLLED PILOT TRIAL.

EUROPEAN JOURNAL OF PEDIATRICS, 2020, 1-10.

AIM

Children with or at risk of faltering growth require nutritional support and are often prescribed oral nutritional supplements (ONS). This randomised controlled trial investigated the effects of energy-dense paediatric ONS (2.4 kcal/ml, 125 ml: cONS) versus 1.5 kcal/ml,200 ml ONS (sONS) in community-based paediatric patients requiring oral nutritional support.

METHODS

Fifty-one patients (mean age 5.8 years (SD 3)) with faltering growth and/or requiring ONS to meet their nutritional requirements were randomised to cONS (n = 27) or sONS (n = 24) for 28 days. Nutrient intake, growth, ONS compliance and acceptability, appetite and gastro-intestinal tolerance were assessed.

RESULTS

Use of the cONS resulted in significantly greater mean total daily energy (+ 531 kcal/day), protein (+ 10.1 g/day) and key micronutrient intakes compared with the sONS group at day 28 and over time, due to high ONS compliance (81% of patients ≥ 75%), maintained intake from diet alone and improved appetite in the cONS group, compared with the sONS group. Although growth increased in both intervention groups, results were significant in the cONS group (weight ($p = 0.007$), height ($p < 0.001$) and height z-score ($p = 0.006$)).

CONCLUSION

This study shows that use of energy-dense (2.4 kcal/ml) low-volume paediatric-specific ONS leads to improved nutrient intakes, growth and appetite in paediatric patients requiring oral nutrition support compared with standard energy density ONS

Link to Full Paper

INTERNAL USE ONLY

GROWTH/EATING CONCERNS
CONSUMER DRIVEN

growth concerns/ picky eaters





GROWTH / EATING CONCERNS

(Parent driven)

growth concerns

- Concern of flattening height/weight gain



Fortini Complete
1.0KCAL/ML
WITH scGOS/lcFOS
(BRAZIL)



Milnutri Sure
1.0KCAL/ML
WITH lcFOS/inulin
(THAILAND/MALAYSIA)

picky eaters

- Limited variety in the diet
- Nutritional inadequacies
- Normal growth



APTAGROW
1+ AGE: 0.66 kcal/ml
3+ & 6+ AGE: 0.71 kcal/ml
WITH scGOS/lcFOS AND *B. breve* M-16V
(ANZ)

GROWTH / EATING CONCERNS

growth concerns

picky eaters

efficacy & other functional claims



product specific data not available



product specific data not available

FORTINI COMPLETE* CLAIMS - GROWTH & APPETITE

product specific data not available



	RESULTS	REFINED CLAIMS
Devaera et al., PGHN 2018*	**Test group:** Fortini/Nutrinidrink MF 1.5 kcal/ml **Control group**: Fortini/Nutrinidrink MF 1.0 kcal/ml No significant differences between the two groups in total weight gain over the 4-week intervention period, daily weight gain, and the % of children who reached a WHZ score of >−1 (Table 3). Total increase in body weight (kg) (1.5 kcal) 0.42±0.40 (1.0kcal) 0.49±0.49 p-value=0.43 About one-third of the children in both groups achieved a WHZ >−1. These children had a higher initial WHZ than those who still had a WHZ <−1 after the 4-week intervention period. Children with milder forms of undernutrition can achieve catch up in weight in around 2 weeks of intervention.	• ONS supports catch up growth in malnourished children** • ONS shows catch up growth in 28 days in malnourished children**



	RESULTS	REFINED CLAIMS
Devaera et al., PGHN 2018*	**Test group:** Fortini/Nutrinidrink MF 1.5 kcal/ml **Control group:** Fortini/Nutrinidrink MF 1.0 kcal/ml There were no significant differences in total energy intake from food consumed between the two groups, both at baseline and day 28. Slightly lower energy intake from solid food after the intervention (−67.62±362.24 kcal in the intervention group and −100.88±391.58 kcal in control group) but this was not significantly different (p=0.67) children with milder forms of undernutrition can achieve catch up in weight in around 2 weeks of intervention.	• ONS improves nutritional intake and does not displace the intake of everyday foods**

*Fortini Complete and Milnutri Sure are 1.0 kcal/ml recipes

** 1.0 kcal/ml, nutritionally complete ONS, p=0.43

FORTINI COMPLETE* CLAIMS - GROWTH & APPETITE

product specific data not available



	RESULTS	REFINED CLAIMS
Devaera et al., PGHN 2018*	**Test group:** Fortini/Nutrinidrink MF 1.5 kcal/ml **Control group**: Fortini/Nutrinidrink MF 1.0 kcal/ml No significant differences between the two groups in total weight gain over the 4-week intervention period, daily weight gain, and the % of children who reached a WHZ score of >−1 (Table 3). Total increase in body weight (kg) (1.5 kcal) 0.42±0.40 (1.0kcal) 0.49±0.49 p-value=0.43 About one-third of the children in both groups achieved a WHZ >−1. These children had a higher initial WHZ than those who still had a WHZ <−1 after the 4-week intervention period. Children with milder forms of undernutrition can achieve catch up in weight in around 2 weeks of intervention.	• ONS supports catch up growth in malnourished children** • ONS shows catch up growth in 28 days in malnourished children**



	RESULTS	REFINED CLAIMS
Devaera et al., PGHN 2018*	**Test group:** Fortini/Nutrinidrink MF 1.5 kcal/ml **Control group:** Fortini/Nutrinidrink MF 1.0 kcal/ml There were no significant differences in total energy intake from food consumed between the two groups, both at baseline and day 28. Slightly lower energy intake from solid food after the intervention (−67.62±362.24 kcal in the intervention group and −100.88±391.58 kcal in control group) but this was not significantly different (p=0.67) children with milder forms of undernutrition can achieve catch up in weight in around 2 weeks of intervention.	• ONS improves nutritional intake and does not displace the intake of everyday foods **in malnourished children****

*Fortini Complete and Milnutri Sure are 1.0 kcal/ml recipes

** 1.0 kcal/ml, nutritionally complete ONS, p=0.43

INTERNAL USE ONLY

FALTERING GROWTH
HCP DRIVEN

tube kids



FALTERING GROWTH

tube kids



efficacy & other functional claims

INTERNAL USE ONLY

FALTERING GROWTH (HCP driven)

tube kids

Nutrini (1-6 years)

Nutrinimax/Tentrini (7-12years)

Energy density	Low energy needs 0,75kcal/mL	Standard energy needs 1kcal/mL	High energy needs 1,5kcal/mL	Standard energy needs 1kcal/mL	High energy needs 1,5kcal/mL
No fibre		 NUTRINI	 NUTRINI ENERGY	 NUTRINIMAX/TENTRINI	 NUTRINIMAX/TENTRINI ENERGY
Fibre 	 NUTRINI LOW ENERGY MF	 NUTRINI MULTI FIBRE	 NUTRINI ENERGY MULTI FIBRE	 NUTRINIMAX/TENTRINI MULTI FIBRE	 NUTRINIMAX/TENTRINI ENERGY MULTI FIBRE
Extensively hydrolised 					

Nutrini Peptisorb Range (1-10years)

 NUTRINI PEPTISORB

 NUTRINI PEPTISORB ENERGY

EVIDENCE OVERVIEW FOR 1+ TUBE

		GROWTH	TOLERANCE	BOWEL FUNCTION / STOOL CONSISTENCY	NUTRITIONAL INTAKE	IMMUNE SYSTEM	OTHER
NUTRINI RANGE	Vernon-Roberts et al., 2010	■		■	■	■	LAXATIVE USE
	Trier et al., 1999	■	■	CONSTIPATION			
	Grogan et al., 2006		■	■			LAXATIVE USE
	Dipasquale et al., 2018	■	■	■			
NUTRINIMAX RANGE	Guimber et al., 2010	■	■	GUT MICROBIOTA			
	Evans et al., 2009	■	■	■	FIBRE INTAKE		
NUTRINI PEPTISORB RANGE	Watling et al., 2008	■	■	■			
	Sorensen et al., 2017	■	■	■			COMPLIANCE

FALTERING GROWTH

tube kids

Nutrini Low Energy Multi Fibre



INTERNAL USE ONLY

Nutrini Low Energy MF OUTCOMES

OUTCOMES RELATED TO **GROWTH**





OUTCOMES RELATED TO **TOLERANCE**

OUTCOMES RELATED TO **NUTRITIONAL INTAKE**





OUTCOMES RELATED TO **IMMUNE SYSTEM**

OUTCOMES RELATED TO **BOWEL FUNCTION**



NUTRINI LOW ENERGY MF CLAIMS - GROWTH & NUTRITIONAL INTAKE

This study includes children with cerebral palsy (CP)

Vernon-Roberts et al., 2010

RESULTS

Single-arm study: Nutrini Low Energy MF 0,75 kcal/ml in gastrostomy tube fed children

There was no significant change in body weight or z score in the period before commencing the low energy feed. There was a significant increase in weight (median difference 1.9kg; p=0.012), mid-upper arm circumference (median difference 1.45cm; p=0.043), and lower leg length (LLL) (median difference 1.62cm; p=0.012)among the participants during the course of the 6-month study (VS baseline), as well as a non-significant increase in upper arm length.

Although skinfold thicknesses increased over the 6-month feeding period, the difference between the values at baseline was not significant for either triceps or subscapular skinfold thickness. There was, however, a significant increase in mid-upper arm circumference (MUAC), suggesting an increase in muscle mass. Linear growth, especially in the lower limbs, was also evident after 6 months.

The increases in weight was not associated with a significant increase in fat mass index (median diff 1.2, p=0.138) or fat-free mass index (median diff 1.4, p=0.138)

REFINED CLAIMS

- Nutrini LE MF **promoted growth** in immobile children with poor growth **(p=0.012)**
- Children without significant growth in the previous 6 months were able to **increase their weight by 20%*** **(p=0.012)**
- Children **increased their weight z score by 0.6** with Nutrini LE MF **(p=0.012)**
- Nutrini LE MF led to **20% weight improvement** in children **without previous growth** **(p=0.012)**
- **Sign improvements in growth markers** were demonstrated [with increase in weight **(p=0.012)**, MUAC **(p=0.043) and** LLL **(p=0.012)**] even when energy intakes were below 75% of the estimated average requirements (consuming Nutrini LE MF)
- A sign. increase in MUAC suggests an i**ncrease in muscle mass (p=0.043)**
- Nutrini LE MF improved growth without an associated misappropriate increase in body fat mass (or fat%) OR promotes good quality of growth
- Adequate nutritional status without an excess deposition of body fat when a low-energy enteral formula is used

Vernon-Roberts et al.,2010

RESULTS

The median percentage intake of the estimated average requirements for energy (kcal) was 43% (interquartile range 23.0) at the beginning of the study and 48.8% (interquartile range 8.5) after 6 months on the low-energy feed.

There was no significant difference between the intake of fat, carbohydrate, and protein at baseline and 6 months after commencing the low-energy feed.

REFINED CLAIMS

- Providing a low energy feed for immobile children with lower energy requirements (such as Nutrini LE MF) **did not compromise intake of protein, fat or micronutrients** ^

*per protocol analysis
^ secondary endpoint

NUTRINI LOW ENERGY MF CLAIMS - BOWEL FUNCTION

This study includes children with cerebral palsy (CP)

	RESULTS	REFINED CLAIMS
Vernon-Roberts et al., 2010	**Single-arm study**: Nutrini Low Energy MF 0,75 kcal/ml in gastrostomy tube fed children Six of the study participants (75%) demonstrated no change in bowel frequency from the baseline to 6-month visit based on the number of times they had their bowels open per week. Although there was a general trend for the use of constipation medication to stay the same, 25% of participants required decreased use of laxative medications after 6 months.	• Bowel frequency was not impacted in **¾ of participants** after using Nutrini LE MF for 6 months^ • There was no impact on bowel frequency in **75% of participants** after using Nutrini LE MF for 6 months^ • **3 in 4 participants** had no impact in bowel frequency after using Nutrini LE MF for 6 months^ • **25% of participants** decreased use of laxative medications after 6 months with Nutrini LE MF^ • **1 in 4 participants** decreased their use of laxatives after 6 months with Nutrini LE MF^ • Laxative medications was reduced in **¼ of participants** after 6 months with Nutrini LE MF^
Grogan et al., 2006	**Test group**: Nutrini LE MF 0,75 kcal/mL or Nutrini EN MF 1,5kcal/mL **Control group**: non-fibre containing baseline formulas Mean stool consistency reduced from 2.4 (range 1.0-3.4) to 1.9 (range 1.3-3.0) at week 4 in Nutrini LEN MF group **1: hard, 2: formed, 3: mushy, 4:runny** Of the 10 children who took regular laxatives, 2 stopped once established in a trial feed	• There was a trend towards a reduction in **stool consistency** in 4 weeks with Nutrini LE MF vs baseline (fiber-free) feed within 4 weeks • **2 out of 10 children** stopped laxative usage after the use of fibre enriched (Nutrini LE MF & Nutrini EN MF)^

^ secondary endpoint

NUTRINI LOW ENERGY MF CLAIMS – TOLERANCE & IMMUNE SYSTEM

This study includes children with cerebral palsy (CP)

	RESULTS	REFINED CLAIMS
Grogan et al., 2006	**Test group:** Nutrini LE MF 0,75 kcal/mL or Nutrini EN MF 1,5kcal/mL **Control group:** non-fibre containing baseline formulas The fibre enriched formulas were as well tolerated as the fibre-free formulae	• Nutrini LE MF was **well tolerated** among pediatric patients receiving tube feeding* (>50% of their energy requirements)^ * Patients were receiving either low energy tube feed (0.75kcal/mL) or high energy (1.5kcal/mL) depending on their needs

	RESULTS	REFINED CLAIMS
Vernon-Roberts et al.,2010	**Single-arm study:** Nutrini Low Energy MF 0,75 kcal/ml in gastrostomy tube fed children The number of chest infections requiring antibiotics decreased in 50% of the participants after 6 months, and 25% had no infections before or after the intervention. Six of the study participants (75%) had no chest infections requiring hospital admission from the beginning of the study to the time of 6-month follow-up, and of the remaining children one had increased, and one had decreased numbers of infections. There was no reported change in chest management between the two study time points.	• **Half of the participants had a reduction in the number of chest infections** requiring antibiotics with Nutrini LE MF^ • **75% of patients (6 out of 8 participants)** receiving Nutrini LE MF had either decreased or no reported chest infections ^ • **3 in 4 patients** receiving Nutrini LE MF had **either decreased or no reported chest infections ^**

^ secondary endpoint

FALTERING GROWTH

tube
kids

Nutrini &
Nutrini
Multi Fibre



INTERNAL USE ONLY

Nutrini & Nutrini MF OUTCOMES

OUTCOMES RELATED TO
GROWTH



OUTCOMES RELATED TO
TOLERANCE



OUTCOMES RELATED TO
BOWEL FUNCTION



NUTRINI MF CLAIMS – GROWTH

This study includes children with cerebral palsy (CP)

	RESULTS	REFINED CLAIMS
Trier et al., 1999	**Test group:** Nutrini MF 1 kcal/ml **Control group:** Nutrini 1 kcal/ml Weight gain was satisfactory in both feeds	• Nutrini & Nutrini MF **supported growth** in tube-fed children*^ • Nutrini & Nutrini MF **led to weight gain in tube-fed children***^
Dipasquale et al., 2018	**Single-arm study**: Nutrini 1 kcal/ml in gastrostomy tube fed children **Tricep skinfold thickness** (SFT) increased substantially in all 38 patients at 12-months follow-up ($p < 0.05$). **Body weight** showed significant increases ($p < 0.05$) in 73% (N = 28) of children at 12-months follow up, while increase was not significant in the remaining 27% (N = 10) children. **BMI** was improved significantly ($p < 0.05$) in 73% (N = 28) of children over the 12-months follow-up. Notably, the group of 28 children who significantly improved in body weight and BMI were those with CP.	• Nutrini lead to **an improvement in the SFT measurement** in all 38 patients** at 12 months follow up **($p < 0.05$).** • Every study patient consuming Nutrini had **improved SFT ($p < 0.05$).** • **73% of the patients** consuming Nutrini had a sign improvement in body weight and BMI **($p < 0.05$)** • **7 out of 10 children** showed a significant increase with their body weight and BMI, while they were using Nutrini **($p < 0.05$)** • **All patients with CP increased their BMI and body weight** while they were using Nutrini over 12 months follow-up **($p < 0.05$)** • **100% of patients** with CP showed **growth improvement** (weight & BMI) with Nutrini **over 12 months follow-up ($p < 0.05$)**

*study population: 16 children requiring tube feeds; 10 with cerebral palsy and 6 with other miscellaneous diagnoses
** study population: 38 neurologically impaired (NI) children – 73% (N = 28) had cerebral palsy (CP); 13% had other diagnoses including metabolic (N = 5) and 13% genetic (N = 5) diseases.
^ secondary endpoint

NUTRINI MF CLAIMS – BOWEL FUNCTION & TOLERANCE

This study includes children with cerebral palsy (CP)

	RESULTS	REFINED CLAIMS
Trier et al., 1999	**Test group:** Nutrini MF 1 kcal/ml **Control group:** Nutrini 1 kcal/ml With the multifibre (MF) feed there was a significant ($p<0.05$) reduction in number of days of constipation (mean constipation 3,69 days in standard feed vs 1,31 in MF feed (mean difference: 2,38days). Changes in the other parameters (e.g stool frequency, diarrhoea, abdominal pain, vomits, transit time) assessed were not significant	• Nutrini MF **improved constipation** among children requiring tube feeding vs non-fiber feed (Nutrini) ($p<0.05$) • Nutrini MF showed a **significant reduction in number of days of constipation** vs non-fibre feed (Nutrini) ($p<0.05$) • Nutrini MF led to a **64%* decrease** in days with constipation vs non-fibre feed (Nutrini)

	RESULTS	REFINED CLAIMS
Trier et al., 1999	**Test group:** Nutrini MF 1 kcal/ml **Control group:** Nutrini 1 kcal/ml Both feeds were well tolerated by all 16 children	• Nutrini & Nutrini MF were **well tolerated** among children with complex medical conditions* requiring tube feeding
Dipasquale et al., 2018	**Single-arm study**: Nutrini 1 kcal/ml in gastrostomy tube fed children None of the children experienced symptoms of feeding intolerance (such as flatulence, distension, and bloating).	• Nutrini was **well tolerated** in neurologically impaired children^ • Nutrini was well tolerated by neurologically impaired children **without accentuation of GI symptoms** ^ • **No feeding intolerance** was observed with Nutrini in neurologically impaired children ^

*study population: 16 children requiring tube feeds; 10 with cerebral palsy and 6 with other miscellaneous diagnoses
! For calculations, please see in the notes section
^ secondary endpoint

FALTERING GROWTH

tube
kids

Nutrini Energy Multi Fibre



Nutrini Energy MF OUTCOMES

OUTCOMES RELATED TO
TOLERANCE



OUTCOMES RELATED TO
BOWEL FUNCTION



NUTRINI ENERGY CLAIMS – BOWEL FUNCTION & TOLERANCE

This study includes children with cerebral palsy (CP)

	RESULTS	REFINED CLAIMS
Grogan et al., 2006	**Test group:** Nutrini LE MF 0,75 kcal/mL or Nutrini EN MF 1,5kcal/mL **Control group:** non-fibre containing baseline formulas Mean stool consistency reduced from 2.5 (range 1.3– 4.0) to 2.2 (range 1.5–4.0) at week 4. Stool consistency improved in 3 children with loose bowel movements showing a clinical improvement. Of the 10 children who took regular laxatives, 2 stopped once established in a trial feed	• There was a trend towards a reduced **stool consistency** in 4 weeks with Nutrini EN MF vs baseline (fiber-free) feed within 4 weeks • **43% of children (3 out of 7 children)** who were on Nutrini EN MF showed a clinically relevant improvement in stool consistency OR a clinically relevant improvement with loose bowel movements • **2 out of 10 children** stopped laxative usage after the use of the fibre enriched tube feed (Nutrini LE MF & Nutrini EN MF)^

	RESULTS	REFINED CLAIMS
Grogan et al., 2006	**Test group:** Nutrini LE MF 0,75 kcal/mL or Nutrini EN MF 1,5kcal/mL **Control group:** non-fibre containing baseline formulas The fibre enriched formulas were as well tolerated as the fibre-free formulae	• **Nutrini EN MF was well tolerated** among pediatric patients receiving tube feeding** (>50% of their energy requirements)^ ** Patients were receiving either low energy tube feed (0.75kcal/mL) or high energy (1.5kcal/mL) depending on their needs

^ secondary endpoint

FALTERING GROWTH

tube kids

Nutrinimax/ Tentrini Range



Nutrinimax/Tentrini Range **OUTCOMES**

OUTCOMES RELATED TO **GROWTH**





OUTCOMES RELATED TO **TOLERANCE**

OUTCOMES RELATED TO **NUTRITIONAL INTAKE**





OUTCOMES RELATED TO **BOWEL FUNCTION**

NUTRINIMAX / TENTRINI CLAIMS - GROWTH & NUTRITIONAL INTAKE

This study includes children with cerebral palsy (CP)

	RESULTS	REFINED CLAIMS
Guimber et al., 2010	**Test group:** Fibre containing feeds [Tentrini MF (1 kcal/mL) or Tentrini EN MF (1,5 kcal/mL)] **Control group:** Fibre-free feeds [(Tentrini (1 kcal/mL) or Tentrini EN(1,5 kcal/mL)] During each phase of the study, children gained weight compared with baseline. No significant changes in height or body composition were observed between the 2 groups.	• Tentrini (EN) MF & Tentrini (EN) **supported weight gain** in children requiring enteral nutrition **(p<0,005)** ^ • **Weight gain was achieved** with Tentrini (EN) MF & Tentrini (EN) in children requiring enteral nutrition (p<0,005)^
Evans et al., 2009	**Test group**: Tentrini EN MF (1,5 kcal/mL) , **Control group**: Tentrini EN (1,5 kcal/mL) All children showed height gain; all but one gained weight and all but three gained MUAC over the study period (out of 25 children).There were no statistically significant changes in Z-scores over the 9-month study.	• Tentrini EN MF & Tentrini EN **supported growth (height)** ^

	RESULTS	REFINED CLAIMS
Evans et al., 2009	**Test group**: Tentrini EN MF (1,5 kcal/mL) , **Control group**: Tentrini EN (1,5 kcal/mL) A significant **more than two-fold increase** in total fibre intake between baseline and each phase of the study when subjects were taking the fibre-containing formula. **More than three-fold increase in total fibre intake** between the fibre-free and fibre-containing formulae during both phases of the study. However, the average intake throughout the study was only 4–5 g day (25–30% of recommended intake) and only a few children met the minimum fibre recommendations.	• Fibre intake was **2 times greater** in patients consuming fibre-containing formula [Tentrini EN MF] vs baseline (p<0,02) ^ • Fibre intake was **3 times greater*** between patients consuming fibre-free (Tentrini EN) & fibre containing formula [Tentrini EN MF] (p=0,003)^ *Despite the higher consumption of fibers via fiber-containing feeds, the total average fiber intake was low; only few children met the minimum fiber recommendations

^ secondary endpoint

NUTRINIMAX / TENTRINI CLAIMS- TOLERANCE

This study includes children with cerebral palsy (CP)

	RESULTS	REFINED CLAIMS
Guimber et al., 2010	**Test group:** Fibre containing feeds [Tentrini MF (1 kcal/mL) or Tentrini EN MF (1,5 kcal/mL)] **Control group:** Fibre-free feeds [(Tentrini (1 kcal/mL) or Tentrini EN(1,5 kcal/mL)] No significant changes in the frequency or severity of GI symptoms (belching, nausea, vomiting, pain, flatulence and bloating) were recorded between the two diets.	• Tentrini (EN) MF & Tentrini (EN) were **well tolerated** among children requiring enteral nutrition, **without accentuation of GI symptoms** ^
Evans et al., 2009	**Test group**: Tentrini EN MF (1,5 kcal/mL) , **Control group**: Tentrini EN (1,5 kcal/mL) Test group: Tentrini EN MF (1,5 kcal/mL) , Control group: Tentrini EN (1,5 kcal/mL). By the end of the study: a) the number of vomits remained unchanged on both formulae; b) nausea was more frequent on the fibre-free formula; and c) bloating was negligible on the fibre-containing formula compared to both the fibre-free formula and at baseline. Abdominal pain was less on both trial formulae than at baseline, but particularly on the fibre-containing formula. None of the tolerance parameters were significantly different between baseline and trial formulae or between the two trial formulae.	• Tentrini EN MF & Tentrini EN were **well tolerated** among tube fed children with a range of medical conditions *^

^ secondary endpoint

* home enterally tube-fed children with a range of medical conditions (21% cystic fibrosis, 21% neurological conditions, 14% liver transplant, 14% crohn's disease , 14% bone marrow transplant, 7% renal disease, 10% other)

NUTRINIMAX / TENTRINI CLAIMS- BOWEL FUNCTION / STOOL CONSISTENCY/LAXATIVE USE

This study includes children with cerebral palsy (CP)

	RESULTS	REFINED CLAIMS
Guimber et al., 2010	**Test group:** Fibre containing feeds [Tentrini MF (1 kcal/mL) or Tentrini EN MF (1,5 kcal/mL)] **Control group:** Fibre-free feeds [(Tentrini (1 kcal/mL) or Tentrini EN(1,5 kcal/mL)] A significant increase in the proportion of stool bifidobacteria (+16,6 %, P<0,05) was observed in the faeces of children in the fibre period than the fibre-free period. Faecal pH was reduced (-0,3) when subjects were fed with fibre (P<0,001). However, this was not accompanied by any significant changes in SCFA levels, possibly due to the very low number of stool samples available for this analysis.	• Tentrini (En) MF led to ~ 17% **increase of stool bifidobacteria** vs the fiber-free feed (Tentrini (En)) • Tentrini (En) MF led to **reduction of stool PH** vs the fiber-free feed (Tentrini (En)) **(p<0,001).**
Evans et al., 2009	**Test group**: Tentrini EN MF (1,5 kcal/mL) , **Control group**: Tentrini EN (1,5 kcal/mL) There was no significant difference between oral or total fibre intake and incidence of diarrhoea or constipation during any phase of the study. By the end of the 2nd phase, constipation occurred less frequently (mean 2.5 versus 3.7 days week) and laxative use was less (mean 2.6 versus 3.8 days week) on the fibre-containing formula vs the fibre-free formula. Laxative dose was generally lower on the fibre-containing formula both in phase 1 and at the end of phase 2 compared to the fibre-free formula. Six out of 10 children had fewer laxatives (frequency and/or dose) on the fibre-containing formula; of the remaining four, two remained the same on both formulae and two children developed constipation (requiring laxative medication) during phase 2 of the study (one on the fibre-free formula and one on the fibre-containing formula).	• Fibre containing feed [Tentrini EN MF] led to **less constipation days** (2,5 days/weeks) vs the fiber-free feed [Tentrini EN] (3,7 days/weeks)* • Fibre containing feed [Tentrini EN MF] led to **32% less constipation days** vs fibre-free feed [Tentrini EN] * • Fibre containing feed [Tentrini EN MF} led to **reduced laxative usage** (2,6 days/weeks) vs fibre-free feed [Tentrini EN} (3,8days/weeks) ***** • Fibre containing feed [Tentrini EN MF] led to **31,5% reduction in laxative usage** vs fibre-free formula [Tentrini EN]* • **Laxative dose** was less on the fibre-containing [Tentrini EN MF] vs the fibre-free feed [Tentrini EN]^ • **6 out or 10 children** reduced the laxatives usage (frequency and/or dose) on the fibre-containing formula [Tentrini EN MF] vs fibre-free feed [Tentrini EN] ^

! For calculations, please see in the notes section

*NS: not statistically significant differences
^ secondary endpoint

FALTERING GROWTH

tube
kids

Nutrini Peptisorb



INTERNAL USE ONLY

Nutrini Peptisorb **OUTCOMES**

OUTCOMES RELATED TO
GROWTH



OUTCOMES RELATED TO
TOLERANCE



OUTCOMES RELATED TO
ACCEPTABILITY



NUTRINI PEPTISORB CLAIMS - GROWTH & NUTRITIONAL INTAKE



	RESULTS	REFINED CLAIMS
Watling et al. 2008	**Test group:** Nutrini Peptisorb (1kcal/mL) **Control group:** Current feed (powdered peptide feed or adult peptide ready-to-use) On average children received 65 kcal/day (11-175) more from the Nutrini Peptisorb (NP) than the current feed (CF). Six children gained weight over the 4 week trial period on the NP, compared to 2 in the CF group. The average change in weight was +0.5kg (-0.4 - +1.4) during the NP period and +0.03kg (-0.5 – +0.8) in the CF period. Baseline measurements: weight 17,3kg, height 103 cm	• Nutrini Peptisorb **increased the nutritional intake** by 65 kcal/d vs current feed^ • **75% of children** (N=8) receiving Nutrini Peptisorb improved their weight VS only 25% of children receiving the current feed^ • **6 out of 8 children** gained weight with Nutrini Peptisorb vs current feed^ • Nutrini Peptisorb lead to **greater weight gain** [+0.5kg (-0.4, +1.4)] vs current feed [+0.03kg (-0.5, +0.8)] after 4 weeks ^



	RESULTS	REFINED CLAIMS
Watling et al. 2008	NP was well tolerated in 86% of the children that received it In some cases, NP reduced GI symptom severity and improved stool consistency.	• Nutrini Peptisorb was well tolerated by **86% of the children** • In some patients, Nutrini Peptisorb **reduced GI intolerance severity** vs current feed • In some patients, Nutrini Peptisorb **improved stool consistency** vs current feed

^ secondary endpoint

NUTRINI PEPTISORB CLAIMS - ACCEPTABILITY

	RESULTS	REFINED CLAIMS
Watling et al. 2008	**Test group:** Nutrini Peptisorb (1kcal/mL) **Control group:** Current feed (powdered peptide feed or adult peptide ready-to-use) NP was reported as being easy to use (6/7), convenient (5/7) and time saving (5/7). When asked their preference of the two feeds, 6 parents reported a preference for the TF.	• The majority of parents reported that **Nutrini Peptisorb** is **convenient & easy to use vs current practice** • **6 out of 8 parents preferred Nutrini Peptisorb** over the current feed

FALTERING GROWTH

tube kids

Nutrini Peptisorb Energy



Nutrini Peptisorb Energy **OUTCOMES**

OUTCOMES RELATED TO
GROWTH



OUTCOMES RELATED TO
TOLERANCE



OUTCOMES RELATED TO
COMPLIANCE



NUTRINI PEPTISORB ENERGY CLAIMS - GROWTH



	RESULTS	REFINED CLAIMS
Sorensen et al., 2017	**Single-arm study**: Nutrini Peptisorb Energy (1,5 kcal/ml) in children with complex medical conditions and impaired absorption/tolerance 80% of patients achieved their primary dietetic goal after receiving the Nutrini Peptisorb Energy (NPE) for 28 days. After receiving the NPE for 28 days •Mean weight significantly increased (+0.33kg, p=0.03) with increases in weight z-score (+0.034, p=0.63) •Mean height increased (+0.72cm, p=0.07) with increases in height z-score (+0.771, p=0.43) At baseline: • Mean weight z-score (-1,373 kg) and mean weight (18,02 kg) • Mean height z-score (-1,80 kg) and mean height (103,87 cm)	• 8 out of 10 children with complex medical conditions* **achieved nutritional goals within 4 weeks** • Nutrini Peptisorb Energy led to **increased weight** (vs baseline) in just 4 weeks (p=0.03) • Nutrini Peptisorb led to **greater weight gain** (vs baseline) in just 4 weeks (p=0.03) • Nutrini Peptisorb Energy led to **~ 2% increase** in weight vs baseline **in just 4 weeks**

* primarily gastrointestinal (GI) (38% i.e. intestinal failure, enteropathy, fistula, atresia), cancer (25% i.e. leukaemia, brain tumour etc), central nervous system (19% i.e. cerebral palsy, epileptic encephalopathy, microcephaly), chronic lung disease (6%), heart failure (6%)

! For calculations, please see in the notes section

NUTRINI PEPTISORB ENERGY CLAIMS – TOLERANCE & COMPLIANCE



	RESULTS	REFINED CLAIMS
Sorensen et al., 2017	**Single-arm study**: Nutrini Peptisorb Energy (1,5 kcal/ml) in children with complex medical conditions and impaired absorption/tolerance At baseline only 4 patients (25%) tolerated their baseline feed without issue. After receiving NPE for 28 days, there were some improvements in GI tolerance (decreases in diarrhoea, abdominal pain, constipation, bloating and burping).	• Nutrini Peptisorb Energy led to some GI symptoms improvements* • In some cases, Nutrini Peptisorb improved GI symptoms OR reduced symptom severity*



	RESULTS	REFINED CLAIMS
Sorensen et al., 2017	Mean compliance with the NPE was high (99%)	• Nutrini Peptisorb Energy led to **99% compliance**^** • **99%** of the children on Nutrini Peptisorb Energy met their prescribed volumes^

*NS: Not statistically significant
**% consumed vs prescribed feed
^ secondary endpoint

INTERNAL USE ONLY

Nutrini & Nutrinimax/Tentrini ABSTRACTS

VERNON-ROBERTS, ANGHARAD, ET AL.

GASTROSTOMY FEEDING IN CEREBRAL PALSY: ENOUGH AND NO MORE.

DEVELOPMENTAL MEDICINE & CHILD NEUROLOGY, 2010, 52.12: 1099-1105.

BACKAGROUND

Gastrostomy feeding children with spastic quadriplegic cerebral palsy (SQCP) improves weight gain but may cause excess deposition of body fat. This study was designed to investigate whether weight gain could be achieved without an adverse effect on body composition by using a low-energy feed in gastrostomy-fed children with SQCP.

METHOD

Fourteen children (7 male; 7 female; median age 2y; range 10mo–11y) with SQCP were studied, 13 of whom were classified as Gross Motor Function Classification Score (GMFCS) level V and one as GMFCS level IV. Children were eligible for the study if they weighed between 8 and 30kg with a diagnosis of severe SQCP and significant feeding difficulties in whom a clinical decision had been made to insert a gastrostomy feeding tube. The feed used in the study had an energy concentration of 0.75kcal ⁄mL (Nutrini Low Energy Multi Fibre). Assessments were performed before gastrostomy insertion (baseline) and after 6 months, and included body composition, growth, nutritional intake, and gastrointestinal symptoms.

RESULTS

There was a significant increase in weight (median difference 1.9kg; 95% confidence interval [CI] 0.85–3.03kg; p=0.012), mid-upper arm circumference (median difference 1.45cm; 95% CI)0.36cm to 3.47cm; p=0.043), and lower leg length (median difference 1.62cm; 95% CI 0.44–3.95cm; p=0.012) over the 6 months. There was no significant increase in fat mass index (median diff 1.21, 95% CI -1.15 to 2.94, p=0.345) or fat free mass index (median diff 1.43, 95% CI -1.15 to 2.94, p=0.249). Micronutrient levels remained within reference ranges with the exception of elevated chromium. The median percentage intake of the estimated average requirements for energy(kcal) was 43% at the beginning of the study and 48.8% after 6 months on the low-energy feed.

CONCLUSION

Children with SQCP who are fed a low-energy, micronutrient-complete, high-fibre feed continue to grow even with energy intakes below 75% of the estimated average requirements. This was not associated with a disproportionate rise in fat mass or fat percentage, and the majority of micronutrient levels remained within the reference range

Link to Full Paper

TRIER, E.; WELLS, J. C. K.; THOMAS, A. G.

EFFECTS OF A MULTIFIBRE SUPPLEMENTED PAEDIATRIC ENTERAL FEED ON GASTROINTESTINAL FUNCTION.

JOURNAL OF PEDIATRIC GASTROENTEROLOGY AND NUTRITION, 1999, 28.5: 595.

BACKGROUND & METHODS

The beneficial effects of fibre on gastrointestinal function are well known but most currently available paediatric enteral feeds do not contain fibre. In order to determine the effects of a new multifibre supplemented enteral feed (Nutrison Paediatric Multifibre, Nutricia) on gastrointestinal function, 16 children requiring tube feeds entered a double-blind cross over study.

The median age of the children was 60 months (range 13-125), 10 had cerebral palsy and 6 had other miscellaneous diagnoses. They were randomised to receive either the multifibre feed or an isocaloric fibre-free feed (Nutrison Paediatric Standard, Nutricia) for 14 days followed by the alternative feed for 14 days. Gut transit time was assessed using a carmine marker.

RESULTS

Weight gain was satisfactory and both feeds were well tolerated by all 16 children. With the multifibre feed there was a significant *($p<0.05$) reduction in number of days of constipation. Changes in the other parameters assessed were not significant.

CONCLUSIONS

The new multibre supplemented feed is well tolerated by children aged 13-125 months requiring tube feeds and significantly reduces the frequency of constipation.

Link to Full Paper

GROGAN, J., ET AL.

GASTROINTESTINAL EFFECTS OF TWO FIBRE ENRICHED PAEDIATRIC ENTERAL TUBE FEEDS.

JOURNAL OF HUMAN NUTRITION AND DIETETICS, 2006, 19.6.

BACKGROUND

Nutrition support is essential in managing many paediatric conditions. Nationally 5300 children receive home enteral tube feeding, and many require feeding for >1 year. To meet children's nutritional requirements a variety of energy densities is required, and it has been shown that dietary fibre is beneficial in pediatrics. The aim of this study was to measure the gastrointestinal(GI) effects of two fibre containing paediatric enteral tube formulas compared to the non-fibre containing baseline formulas. The trial feeds were a low energy (0.75 kcal mL-I; Nutrini Low Energy Multi Fibre, Nutricia), and a high-energy (1.5 kcal mL-1; Nutrini Energy Multi Fibre, Nutricia) formula.

METHODS

Children were recruited if they received >50% of their energy requirements from an enteral feed which they had been stable on for >3 months. Children were excluded if they received parenteral feeding, were terminally ill, or a fibre feed was contraindicated. Children remained on their existing non-fibre regimen for 1 week (baseline), before changing to a fibre enriched trial feed for 4 weeks. Data collected included, weight, height, medications and GI effects. Stool frequency and consistency were recorded for 7-day periods. Stool consistency scores were 1; hard, 2; formed, 3; mushy, 4; runny.

RESULTS

Seven children completed 4 weeks on the high energy formula. Mean stool frequency at baseline was 1.3 (range 0.1-2.4) compared to 1.5 (range 0.4-2.1) at week 4. Mean stool consistency reduced from 2.5 (range 1.34.0) to 2.2 (range 1.5-4.0) at week 4. Stool consistency improved in three children with loose bowel movements showing a clinical improvement. Seven children completed 4 weeks on the low energy formula. Mean stool frequency at baseline was 0.85 (range 0.6-1.4) compared to 0.9 (range 0.3-2.1) at week 4. Mean stool consistency reduced from 2.4 (range 1.0-3.4) to 1.9 (range 1.3-3.0) at week 4. Reduced nausea/vomiting was reported in one child and reduced abdominal pain in another. Of the 10 children who took regular laxatives, two stopped once established on a trial feed.

CONCLUSIONS

The fibre-enriched formulas were well tolerated in this small sample of paediatric patients; however further research from an appropriately powered trial is required.

Link to Full Paper

DIPASQUALE, VALERIA, ET AL.

STANDARD POLYMERIC FORMULA TUBE FEEDING IN NEUROLOGICALLY IMPAIRED CHILDREN: A FIVE-YEAR RETROSPECTIVE STUDY.

NUTRIENTS, 2018, 10.6: 684.

BACKGROUND

Malnutrition is frequent in neurologically impaired (NI) children. Enteral feeding via gastrostomy tube is increasingly being used to provide adequate nutrition. Our aim was to assess the outcomes of exclusive gastrostomy tube feeding with standard polymeric formula in children with NI, severe oro-motor dysfunction, and malnutrition, and to investigate the role of the underlying NI-associated disease.

METHODS

A five-year retrospective study from January 2013 to November 2017 was conducted. The primary aim was to assess the nutritional outcomes of exclusive gastrostomy tube feeding with standard polymeric formula in malnourished NI children. The secondary aim was to investigate gastrostomy complications and the impact of the underlying NI-associated disease on the nutritional outcomes.

RESULTS

We enrolled 110 consecutive children with NI. Of these patients, 34.5% (N = 38) were categorized as malnourished and started exclusive enteral feeding with a standard (1.0 kcal/mL) polymeric formula (Nutrini, Nutricia) after percutaneous endoscopic gastrostomy (PEG) placement. Seventy-three percent of patients (N = 28) had cerebral palsy (CP); other diagnoses included metabolic (13%, N = 5) and genetic (13%, N = 5) diseases. Tricep skinfold thickness had significantly improved in all patients at 12-months follow-up, while body weight and body mass index showed significant increases mainly in children with CP. No serious complications occurred.

CONCLUSIONS

We found that standard polymeric formula via gastrostomy tube represents a safe and efficient nutritional intervention in children with NI and malnutrition.

Link to Full Paper

EVANS, S., ET AL.

FIBRE CONTENT OF ENTERAL FEEDS FOR THE OLDER CHILD.

JOURNAL OF HUMAN NUTRITION AND DIETETICS, 2009, 22.5: 414-421.

BACKGROUND

There is currently a lack of clinical data on fibre requirements in UK children. Subsequently, the ideal fibre profile for enteral formulae designed to meet the requirements of older children is unknown. The present study aimed to investigate the effect of fibre supplementation on gastrointestinal function of children aged 7–12 years (or weight 21–45 kg) receiving an age-specific high-energy enteral feed.

METHODS

In this double-blind randomised crossover study, 25 home enterally tube-fed children with a range of medical conditions (including cystic fibrosis, neurological conditions, liver transplant and bone marrow transplant) were given a 1.5 kcal mL)1 formula with or without added dietary fibre (1.13 g per 100 mL). Each formula was taken for 6 weeks, followed by 6 months on the second randomly assigned formula. Anthropometry, blood biochemistry, stool characteristics, tolerance and oral dietary intake were assessed.

RESULTS

Despite a higher median fibre intake on the fibre-containing formula (84% versus 26% of recommended intake; P = 0.003), most children did not meet existing international recommendations for fibre as a result of small feed volumes (median 800 mL day)1; 9 g fibre day)1). There was some evidence of reduced constipation, laxative reliance and abdominal pain on the fibrecontaining formula.

CONCLUSIONS

Given the poor fibre intakes and absence of adverse effects, the use of fibre-containing formulae should become standard practice for the majority of children on enteral feeds. Larger trials in children are required to further evaluate the effect of amount and blend of fibre in enteral formulae for older children. However, it is likely that current formulae require higher levels of fibre.

Link to Full Paper

GUIMBER, DOMINIQUE, ET AL.

EFFECT OF MULTI FIBER MIXTURE WITH PREBIOTIC COMPONENTS ON BIFIDOBACTERIA AND STOOL PH IN TUBE-FED CHILDREN.

BRITISH JOURNAL OF NUTRITION, 2010, 104.10: 1514-1522.

BACKGROUND

The objective of the present study was to evaluate the effect of a paediatric tube feed supplemented with a multi fibre mixture on the gut microbiota and nutritional and micronutrient status of children on long-term enteral nutrition (EN).

METHODS

A randomised, controlled, double-blind, cross-over trial (2 £ 3 months) with a washout period of 1 month was carried out. Twenty-seven children (80% neurologically impaired) aged 11·9 (SD 3·9) years, on long-term EN (4·8 (SD 3·9) years) were recruited. The analyses of the children's faecal pH, microbiota along with anthropometric measures, bowel movements and markers of blood micronutrient status were made.

RESULTS

Twenty children completed the study. A significant increase in the proportion of stool bifidobacteria (þ16·6 %, P,0·05) was observed during the multifibre period than during the fibre-free period, together with a significant reduction in stool pH (P<0,001). Stool frequency and consistency as well as growth did not differ between the two periods. There was a significant increase (P,0·05) in plasma ferritin at the end of the fibre-free period, but plasma ferritin levels remained within normal ranges during both periods. No diet effects on other blood parameters were observed.

CONCLUSIONS

In conclusion, addition of a multi fibre mixture with prebiotic components to paediatric EN is well tolerated, promotes bifidobacteria and reduces stool pH, indicating an improved gut health.

Link to Full Paper

INTERNAL USE ONLY

Nutrini Peptisorb ABSTRACTS

WATLING R, GROGAN J ET AL.

GASTROINTESTINAL TOLERANCE AND CONVENIENCE OF A NEW READY-TO-USE PAEDIATRIC PEPTIDE FEED

(POSTER AT BSPGHAN, 2008)

BACKGROUND

Peptide based enteral feeds may be beneficial for patients with malabsorption disorders. In the UK peptide based formulae are currently limited to adult peptide ready-to feed, powdered peptide infant (<1y) and powdered peptide (1-6y) formulae. None of these feeds are ideal for children (1-6y). Adult feeds provide excessive, and infant feeds insufficient, amounts of protein and some micronutrients. Furthermore, infant feeds provide insufficient energy. When compared to ready-to-use formulae, powdered formulae may have reconstitution risks such as contamination, handling errors and increased time to prepare.

METHOD

Gastrointestinal (GI) tolerance and convenience of a new ready-to-use enteral peptide feed (1kcal/ml) formulated specifically for children (8-30kg) was assessed in an open label, randomised, controlled, cross-over study. Eight children age 5 (1-9) y ; weight 17.3 (11.3-24.2) kg; height 103 (82-125) cm; 3 with short bowel syndrome, 3 with cystic fibrosis and 2 with renal disease) were recruited from 4 UK centres. Eligible children were randomised to receive either their current feed (CF) or the trial feed (TF: Nutrini Pepti, Nutricia) for 4 weeks in a random order (total trial period 8 weeks). GI tolerance (nausea, vomiting, abdominal distension, burping, flatulence, constipation, diarrhoea) was recorded daily during weeks 2-4 and weeks 6-8, as well as the number and consistency of bowel motions. Anthropometric measures were assessed at weeks 0, 4 and 8. Feed intake was recorded daily. At the end of week 4 and week 8, parents completed a questionnaire to evaluate the feed convenience and preference.

RESULTS

The TF was well tolerated in 86% of the children that received it (1 dropped out upon crossing over onto the TF). In some cases the TF reduced GI symptom severity and improved stool consistency. Six children gained weight over the 4 week trial period on the TF, compared to 2 in the CF group. The average change in weight was +0.5kg (-0.4 - +1.4) during the TF period and +0.03kg (-0.5 – +0.8) in the CF period. On average children received 65 kcal/day (11-175) more from the TF than the CF. The TF was reported as being easy to use (6/7), convenient (5/7) and time saving (5/7). When asked their preference of the two feeds, 6 parents reported a preference for the TF.

CONCLUSIONS

This small trial suggests that a new paediatric, ready-to-use peptide feed was well tolerated in children with varying pathologies. When compared to the more complex current feeding regimens, parents preferred the ready-to-use peptide feed for its convenience and ease of use.

Link to Full Paper

SORENSEN K, AMANDA JUDD ET AL.

CLINICAL COMPLEXITIES AND DIETETIC OUTCOMES OF PAEDIATRIC PATIENTS RECEIVING A HIGH ENERGY, PEPTIDE-BASED TUBE FEED FOR 4 WEEKS

(POSTER AT ESPGHAN, 2017)

BACKGROUND

Nutrient malabsorption can result from disease or its treatment, contributing to faltering growth in paediatric tube-fed patients. Peptide-based tube feeds (PTF) containing hydrolysed protein (peptides, measured in kilodaltons (kDa)) and medium chain triglycerides (MCT) can be used to manage faltering growth in paediatric patients with malabsorption and feeds with a higher proportion of smaller peptides may improve nutrient absorption. This study aimed to explore the complex medical conditions and dietetic outcomes of paediatric patients receiving a high energy PTF (HEPTF) with 91% of peptides <1.5kDa & 52% MCT.

METHODS

16 patients (mean age 6yr 5mo), mean weight z-score -1.373±2.15) were recruited from UK hospitals (n=6, 38%), outpatient clinics (n=5, 31%) and community services (n=5, 31%) onto this prospective, longitudinal study. Patients received a HEPTF (1.5kcal/ml, Nutrini Peptisorb Energy, Nutricia) for 28 days. All patients had complex clinical conditions with multiple diagnoses. All patients had impaired absorption or tolerance with GI symptoms such as diarrhoea, constipation, abdominal pain and vomiting, either secondary to their medical condition or its treatment. Primary dietetic goals for 4wks on the HEPTF were growth (50%), growth and tolerance (31%) and tolerance (19%).

RESULTS

At baseline, 12 patients (75%) were already receiving a PTF (1kcal/ml n=7, 44%; 1.5kcal/ml n=5, 31%) and 4 (25%) were receiving a polymeric tube feed (1kcal/ml n=1, 6%; 1.5kcal/ml n=3, 19%), via nasogastric or gastrostomy tube. Only 4 patients (25%) tolerated their baseline feed without issue, and no patients receiving polymeric feeds at baseline tolerated these well. Whilst receiving the HEPTF, decreases in diarrhoea, abdominal pain, constipation, bloating and burping were reported (NS). Compliance was high (mean 99%). Mean energy and protein intakes were maintained (+111kcal/d (p=0.15); +0.5g/d protein (p=0.89)). Weight significantly increased (+0.33kg, p=0.03), with increases in weight z-score (+0.034, p=0.63), height (+0.72cm, p=0.07) and height z-score (+0.771, p=0.43) after 28 days. 80% of patients achieved their primary dietetic goal.

CONCLUSIONS

This group of paediatric patients requiring PTF with complex clinical conditions achieved good tolerance, high feed compliance and significant weight gain with the HEPT increases were nominal, it is possible that the significant weight gain was due to improved absorption aided by the high proportion of small peptides in the HEPTF (91% but further explorative research is needed.

Link to Full Paper

MARKET POSITION CLAIMS

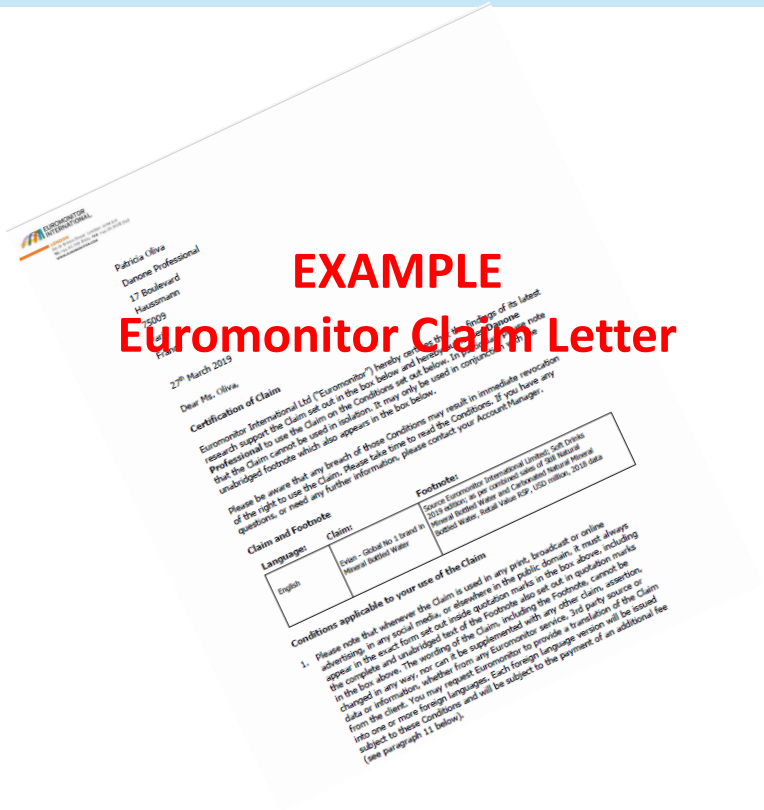
The following MARKET POSITION CLAIMS were built and disseminated in 2021 May MAT. As such all data are based on the market position in 2021. Based on consolidated reports from multiple market audit sources e.g Nielsen & IQVIA for the period May MAT.

EVIDENCE TO SUBSTANTIATE

SUBJECT TO CONFIRMATION FROM THE COUNTRIES

DEAR COUNTRIES, PLEASE CONFIRM WHETHER YOU ARE PLANNING TO USE THE MARKET POSITION CLAIMS THAT ARE PROVIDED IN THE COMING SLIDES. BASED ON YOUR FEEDBACK, THE GLOBAL TEAM WILL COVER THE COSTS FOR THE SUBSTANTIATION– CLAIM LETTER FROM EUROMONITOR & IQVIA

#1 MARKET PERFORMANCE IN EU CLAIM CAN ONLY BE MADE IF YOU ARE ALSO #1 IN YOUR MARKET (APPLICABLE TO EU ONLY)



EXAMPLE

Euromonitor Claim Letter

Patricia Oliva
Danone Professional
17 Boulevard
Haussmann
75009
France

27th March 2019

Dear Ms. Oliva,

Certification of Claim

Euromonitor International Ltd ("Euromonitor") hereby certifies that, to the best knowledge of its latest research support the Claim set out in the box below and hereto, the Claim may be used by Danone Professional to use the Claim on the Conditions set out below. In Footnote which also appears in the box below. that the Claim cannot be used in isolation. It may only be used in conjunction with the unabridged footnote which also appears in the box below.

Please be aware that any breach of those Conditions may result in immediate revocation of the right to use the Claim. Please take time to read the Conditions. If you have any questions, or need any further information, please contact your Account Manager.

Claim and Footnote

Language:	Claim:	Footnote:
English	Evian - Global No 1 brand in Mineral Bottled Water	Source Euromonitor International Limited; Soft Drinks 2019 edition; as per constrained sales of Still Natural Mineral Bottled Water and Carbonated Natural Mineral Bottled Water, Retail Value RSP, USD million, 2018 data

Conditions applicable to your use of the Claim

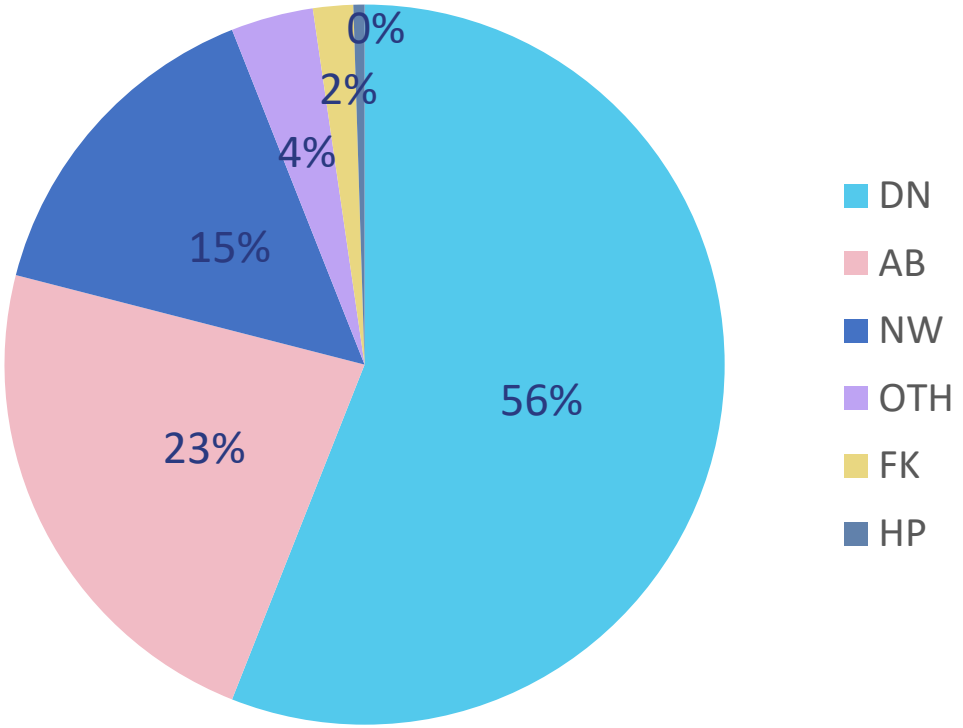
1. Please note that whenever the Claim is used in any print, broadcast or online advertising, in any social media, or elsewhere in the public domain, it must always appear in the exact form set out inside quotation marks in the box above, including the complete and unabridged text of the Footnote also set out in quotation marks in the box above. The wording of the Claim, including the Footnote, cannot be changed in any way, nor can it be supplemented with any other claim, assertion, data or information, whether from any Euromonitor services, 3rd party source or from the client. You may request Euromonitor to provide a translation of the Claim into one or more foreign languages. Each foreign language version will be issued subject to these Conditions and will be subject to the payment of an additional fee (see paragraph 11 below).

SUBJECT TO RECEIVE EUROMONITOR CLAIM LETTER - INTERNAL USE ONLY

EUROPE – TOTAL PAEDIATRIC TUBE & ONS

Category: PAEDS. SPEC | Region: EUROPE | Country: ALL | Year: 2021 | Measure: VALUE (MILLION EURO) | Segment: GROWTH | Sub-Segment: CHALLENGED GROWTH | Sub-Sub-Segment ALL | Stage: ALL

- #1 in Europe Paediatric TUBE & ONS range for Faltering Growth / Malnutrition
- Leader in Europe for dietary management of Faltering Growth / Paediatric Malnutrition

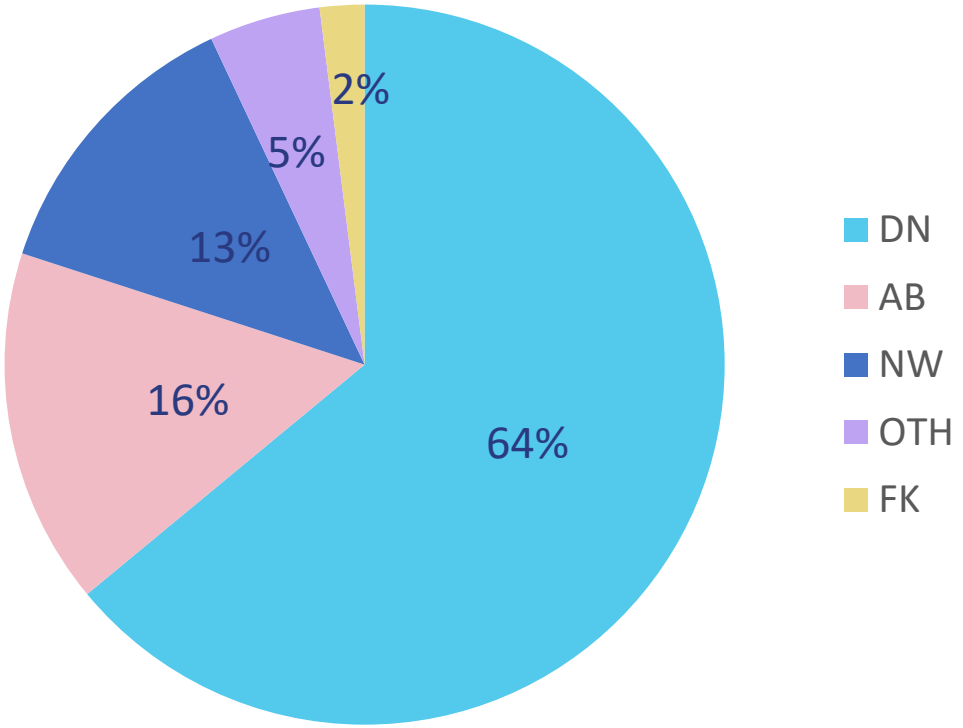


SUBJECT TO RECEIVE EUROMONITOR CLAIM LETTER - INTERNAL USE ONLY

EUROPE – TOTAL PAEDIATRIC TUBE

Category: PAEDS. SPEC | Region: EUROPE | Country: ALL | Year: 2021 | Measure: VALUE (MILLION EURO) | Segment: GROWTH | Sub-Segment: CHALLENGED GROWTH | Sub-Sub-Segment UP AGE TUBE | Stage: ALL

- #1 company in Europe for Paediatric Tube Nutrition
- NUTRINI #1 brand in Europe for Paediatric Tube Nutrition
- NUTRINI Europe Leader for Paediatric Tube Nutrition

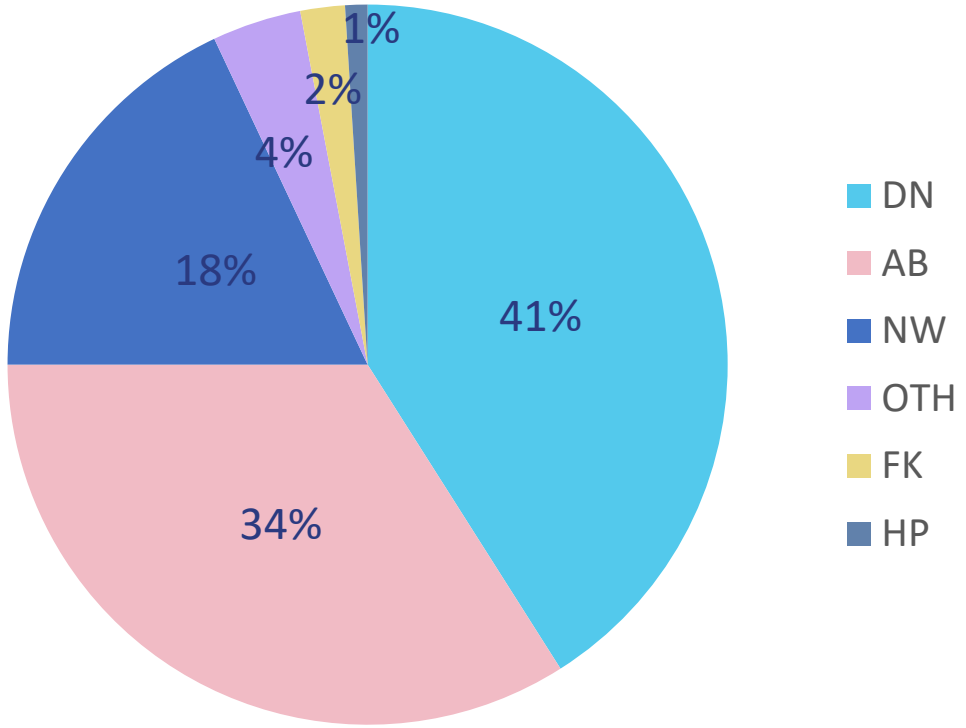


SUBJECT TO RECEIVE EUROMONITOR CLAIM LETTER - INTERNAL USE ONLY

EUROPE – TOTAL PAEDIATRIC ONS

Category: PAEDS. SPEC | Region: EUROPE | Country: ALL | Year: 2021 | Measure: VALUE (MILLION EURO) | Segment: GROWTH | Sub-Segment: CHALLENGED GROWTH | Sub-Sub-Segment UP AGE ORAL | Stage: ALL

- #1 company in Europe for Paediatric Oral Nutritional Supplements (ONS)
- Europe Leader in Oral Nutritional Supplements for dietary management of Faltering Growth / Paediatric Malnutrition
- Europe Leader in Oral Nutritional Supplements for catch-up growth

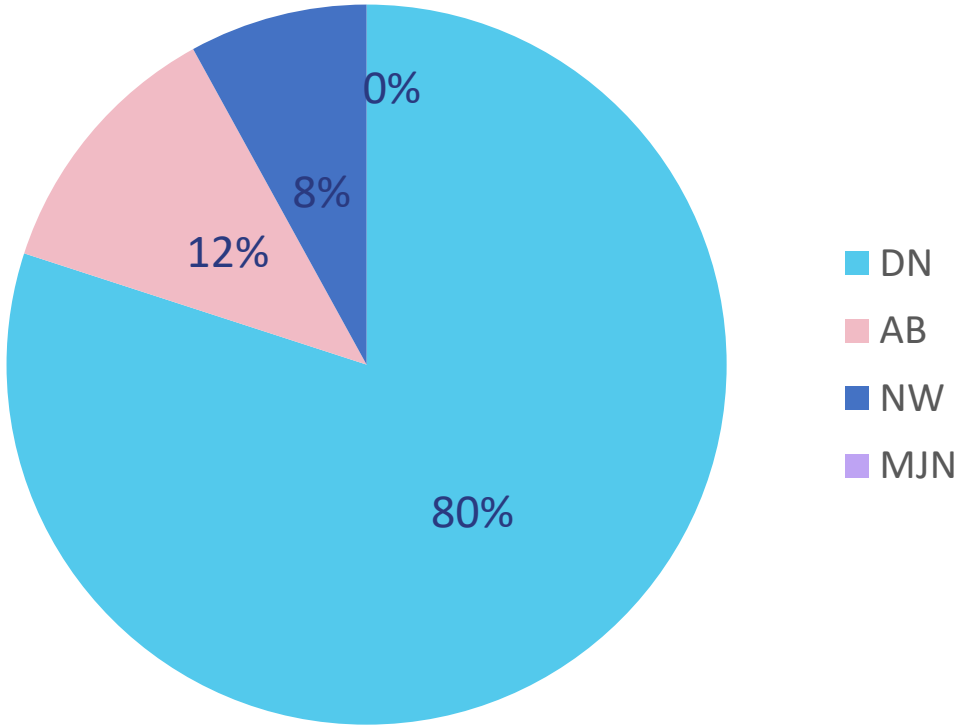


SUBJECT TO RECEIVE EUROMONITOR CLAIM LETTER - INTERNAL USE ONLY

GLOBAL – INFANT FALTERING GROWTH / MALNUTRITION

Category: PAEDS. SPEC | Region: GLOBAL | Country: ALL | Year: 2021 | Measure: VALUE (MILLION EURO) | Segment: GROWTH | Sub-Segment: CHALLENGED GROWTH | Sub-Sub-Segment INFANTS | Stage: ALL

- Global Leader for dietary management of Faltering Growth / Malnutrition among infants
- #1 in the world for dietary management of Faltering Growth / Malnutrition among infants
- #1 Energy-Nutrient Dense Infant Feed



FURTHER KEY NOTES

- A “No.1” claim denotes that a product or service is the best-selling on the market, and we should take care to ensure that we hold sufficient evidence to prove that claim.
- A “No.1” claim is, by its nature, likely to be seen as a comparison against all competitors on the market, unless specific competitors are named.
- The nature of the evidence required to substantiate these claims will vary depending on the context in which the claim is made and how it is likely to be understood by its audience, but in all such cases it is likely that comparative evidence relating to unit-sales, market share or overall sales turnover figures will be required.
- The disclosure accompanying “No.1" claim should contain source of data (e.g. “based on Euromonitor data”), identify the time period and the scope of the claim.
- We should carefully consider where to make “No. 1” claims (e.g. in advertisements, website, at-shelf displays, product packaging, etc.).
- Market leadership claims are subject to the local legislation(s). A local assessment required for each claim.
- #1 market performance in EU claim can only be made if you are also #1 in your market (applicable to EU only)

FURTHER KEY NOTES

CLAIM	DATA	DISCLAIMER
PAEDIATRIC TUBE CLAIMS	Data in Europe	* Among the brands of paediatric tube-feeds. Based on data reported by Euromonitor International Limited, Packaged Food 2021 edition, value sales RSP, 2021 May MAT data → TBC with the CLAIM LETTER FROM EUROMONITOR & IQVIA
PAEDIATRIC ONS CLAIMS	Data in Europe	* Among the brands of paediatric oral nutritional supplements. Based on data reported by Euromonitor International Limited, Packaged Food 2021 edition, value sales RSP, 2021 May MAT data → TBC with the CLAIM LETTER FROM EUROMONITOR & IQVIA
INFANT FALTERING GROWTH / MALNUTRITION CLAIMS	Data Global	* Among the brands of energy-nutrient dense feeds for management of faltering growth / malnutrition among infants. Based on data reported by Euromonitor International Limited, Packaged Food 2021 edition, value sales RSP, 2021 May MAT data → TBC with the CLAIM LETTER FROM EUROMONITOR & IQVIA

B BRAND EQUITY CLAIMS

The following BRAND EQUITY CLAIMS were built and disseminated based on a quantitative market study with field work conducted in January 2021 among pediatricians and Dieticians in Germany, Spain, Netherlands and UK .

SUPERIORITY COMMUNICATION TERRITORIES

1. Complete nutrition in tolerable volume for pediatric patients to grow (weight/height gain)
2. Evidence based / Clinically effective
3. Supports immune system development, as well as weight and height gain
4. Supports brain & cognitive development, as well as weight and height gain
5. Provides age, nutritional need, health condition adapted nutritional solutions

HCP PERCEPTION CLAIMS

AMONG PEDIATRICIANS & DIETITIANS WHO KNOW THE BRAND

BRAND POWER & CREDIBILTY	**TRUSTED BY** 90% of Pediatricians in Europe (**9 out of 10** Pediatricians in Europe **TRUST FORTINI)**
	More than **90%** of European Pediatricians **recommend it to their peers**
	Perceived as **an expert in Nutrition and Healthy Growth** by **more than 80% of Pediatricians in Europe**
EFFICACY	**Noticeable Growth** by More than 80% of pediatricians in Europe
	8 out of 10 EU pediatricians, observed **parents' satisfaction with weight gain results**
	According to EU Pediatricians, **parents are more satisfied with weight gain results compared to Pediasure**
	8 out of 10 EU pediatricians, observed **parents' reassurance with filling nutritional gaps.**
	According to EU Pediatricians, **parents are more reassured with filling nutritional gaps vs Pediasure**
	8 out of 10 EU Pediatricians **noticed Visible Growth with FORTINI**
	"Parents are satisfied with weight and height gain" as noticed **by 8 out of 10 of Peds in EU**
	SATISFYING WEIGHT AND HEIGHT GAIN, as noticed by 80% of pediatricians in Europe
UX	**8 out of 10** Pediatricians in Europe perceived Fortini **as well accepted by children**

1 SERMO Quantitative Survey in Germany, Spain, Netherlands, UK; 212 pediatricians* and dieticians* participated; January 2021
* who know the brand & prescribe ONS for management of faltering growth

ONS CATEGORY TOP DRIVERS

EFFICACY, COMPLETE NUTRITION AND TAILORED SOLUTIONS, ALONG WITH IMMUNE & BRAIN BENEFITS ARE RANKED AS TOP 5






Which statement(s) do you consider most important to make your decision on which ONS brand to Rx for FG:	N=50	N=50	N=82	N=30	Global Rank**
I trust the brand	52%	44%	43%	47%	14
Requested by parent or carer	20%	16%	7%	13%	16
Recommended by a colleague	20%	22%	27%	47%*	13
Available on the formulary	34%	58%	78%*	20%	8
Evidence based / Clinically effective	82%	82%	80%	70%	2
Cost effective management	34%*	70%	77%	63%	11
Provides complete nutrition in tolerable volume for pediatric patients to grow (weight/height gain)	82%	70%	84%	70%	1
Helps my pediatric patients to recover	64%	64%	66%	70%	6
Supports immune system development, as well as weight and height gain	74%	60%	48%	73%	3
Supports brain & cognitive development, as well as weight and height gain	74%	68%	54%	67%	4
Provides a wide range of different formats, flavors, textures to support compliance	76%	64%	73%	83%	7
My patients like the taste	62%	68%	78%	80%	10
Supports overall appetite of my patients	18%	34%	54%*	23%	15
Supports/led increase in nutritional intake from everyday food	64%	60%	56%	67%	9
I observe positive results in overall wellbeing of my pediatric patients	60%	62%	60%	60%	12
Provides age, nutritional need, health condition adapted nutritional solutions	90%	76%	82%	83%	5

*SIGN HIGHER/LOWER IN A MARKET
GREEN COLORING SHOWS >70% SCORES
YELLOW COLORING SHOWS BETWEEN 50-70% SCORES

**DEFINED BY %HCPS ADDING CLAIM IN THEIR TOP 5

FORTINI PERFOMANCE VS COMPETITION

GLOBAL SCORE CARD



	PERFORMANCE ON CLAIMS (TOP 2 BOX HCPS AGREEING)	DE ES UK NL	ES UK NL	ES	UK	DE
BRAND	2 Is **evidence/research based**					
	Has **high quality** standards					
	Is an **expert** in nutrition, supporting children to grow healthy					
	I **trust the brand**					
	Parents are **satisfied overall with the brand**					
EFFICACY	Helps my pediatric patients to **recover**					
	I observe **positive results in overall wellbeing** of my pediatric patients					
	I observe **noticeable growth improvement** in my pediatric patients					
	Parents are satisfied with the **weight and/or height gain**					
	Parents are reassured that it helps **fill nutritional gaps**					
	Parents are reassured that it helps their child **recover faster**					
ACCEPTANCE	1 Provides **complete nutrition in tolerable volume** for pediatric patients to grow (weight/height gain)					
	Well accepted by children – not face digestive discomfort					
	My patients **like the taste**					
	Their child **likes the products**					
	Their child **likes the taste**					
WIDE RANGE	5 Provides a **wide range** of different formats, flavors, textures to support compliance*					
	Gives *parents* **different alternatives**; format, flavors, textures					
STIMULATING APPETITE	Supports overall **appetite** of my patients					
	Supports/led increase in **nutritional intake** from everyday food					
	Helps improve *their child's* **appetite**					
ADD. BENEFITS	3 Supports **immune system development**, as well as weight and height gain					
	4 Supports **brain & cognitive development**, as well as weight and height gain					
EMOTIONAL BENEFITS	Gives *parents* confidence they are **doing the right thing** for their child					
	Helps *their child* to be **active, playful, happy**					

COUNTRY SELECTION BASED ON >50% AWARENESS

All markets >80% agreement
3/4 markets >80% agreement
3/4 markets <60% agreement
All markets <60% agreement

SUPPORTING INFORMATION

SAMPLE SPECIFICATIONS PER MARKET

		 DE	 ES	 UK	 NL
SPECIALTY	Pediatrician	100%	88%	61%	100%
	Dietician	-	-	39%	-
	Gastroenterologists (paed)	-	12%	-	-
	Total sample	**50**	**50**	**82**	**30**
YEARS IN PRACTIVE	Average years	21	19	19	20
NUMBER OF CHILDREN TREATED	1-3 years	76	73	25	24
	4-10 years	82	76	23	28
HEALTH TOPIC SEEN PER MONTH (by % of HCPs)	Faltering growth	100%	100%	100%	100%
	Concerns about child's nutrition	100%	94%	98%	93%
	Overweight or obesity	98%	90%	78%	97%

SUPPORTING INFORMATION

AWARENESS & PRESCRIPTION ON FULL SAMPLE (INCL. SCREEN-OUTS)



	Awareness (n=55)
Fortini	98%
Pediasure	18%
Resource Junior	24%
Peptamen Junior	38%
Frebini drink	84%



	Awareness (n=158)
Fortini	54%
Pediasure	99%
Resource Junior	90%
Peptamen Junior	41%
Frebini drink	-



	Awareness (n=119)
Fortini	97%
Pediasure	96%
Resource Junior	41%
Peptamen Junior	82%
Frebini drink	18%



	Awareness (n=32)
Fortini	100%
Pediasure	75%
Resource Junior	25%
Peptamen Junior	25%
Frebini drink	22%

Awareness for competitors remains fairly similar between full sample vs. screened sample, providing confidence that the results are representative.
Main difference is that awareness for Fortini is lower in Spain.

SUPPORTING INFORMATION

BRAND AWARENESS AND PRESCRIPTION AMONG HCPS



N		Awareness	OF THOSE AWARE: Prescription	Rx Most Often	Rx to peers
50	Fortini*	100%	100%	69%	94%
2	Pediasure	20%	40%	50%	50%
4	Resource Junior	24%	50%	—	75%
12	Peptamen Junior	40%	70%	8%	83%
34	Frebini drink	86%	84%	32%	94%



N		Awareness	OF THOSE AWARE: Prescription	Rx Most Often	Rx to peers
50	Fortini*	100%	100%	21%	92%
39	Pediasure	98%	92%	42%	100%
38	Resource Junior	96%	96%	49%	100%
13	Peptamen Junior	62%	77%	8%	100%
-	Frebini drink	-	-	0%	-



N		Awareness	OF THOSE AWARE: Prescription	Rx Most Often	Rx to peers
82	Fortini*	100%	100%	41%	99%
68	Pediasure	95%	95%	56%	99%
20	Resource Junior	46%	66%	20%	85%
28	Peptamen Junior	84%	58%	10%	96%
4	Frebini drink	15%	50%	41%	100%



N		Awareness	OF THOSE AWARE: Prescription	Rx Most Often	Rx to peers
30	Fortini*	100%	100%	80%	100%
13	Pediasure	73%	64%	8%	100%
2	Resource Junior	27%	50%	0%	100%
4	Peptamen Junior	27%	75%	25%	100%
5	Frebini drink	23%	86%	20%	100%

*NOTE: HCPS HAD TO BE AWARE AND PRESCRIBE FORTINI IN ORDER TO BE ABLE TO PARTICIPATE FOR THE SURVEY

HERITAGE CLAIMS

The following HERITAGE CLAIMS were built and disseminated in 2021. As such all dates and time periods (for e.g., '*10 years of research on X*') are correct as of 2021. As of 2022 these time periods will be one year longer (e.g., '*11 years of research on X*'). Including the calendar year used as a reference point for each claim. Please ensure to revise the time period for claims in line with the substantiation date if using beyond 2022

Infatrini HERITAGE CLAIMS



1999

Infatrini launched

- 22 years of Infatrini use in the EU
- 22 years supporting infants with faltering growth / malnutrition in the EU

2006

1st publication with **Infatrini***

- 15 years of Infatrini research
- 15 years of scientific research among infants with faltering growth / malnutrition

2007

Nutricia introduced the unique prebiotic blend scGOS:lcFOS (9:1) to **Infatrini**

- 14 years of experience with the unique prebiotic blend scGOS:lcFOS (9:1) in infants with faltering growth / malnutrition

* Evans S, et al. J Hum Nutr Diet 2006;19:191-97

Fortini / Nutrinidrink HERITAGE CLAIMS

2003

Fortini launched

- 18 years of Fortini in the EU – the high energy sip feed range for malnourished children



2004

1st publication with **Fortini**

- 17 years of Fortini research


Is fibre supplementation in paediatric sip feeds beneficial?

2010

Fortini Smoothie Multi Fibre launched

- The 1st and ONLY nutritionally complete smoothie for the dietary management of malnourished children



2014

Fortini Creamy Fruit launched

- The 1st and ONLY nutritionally complete dessert style supplement for the dietary management of malnourished children



2017

Fortini Compact Multi Fibre launched*

- The 1st paediatric compact product for the dietary management of malnourished children*



2020

Fortini Compact Multi Fibre publication**

- Nutricia's 1st publication on Fortini Compact Multi Fibre


Energy-dense, low-volume paediatric oral nutritional supplements improve total nutrient intake and increase growth in paediatric patients requiring nutritional support: results of a randomised controlled pilot trial

* Launched in EU 2017
** Hubbard et al. 2020

Paediatric tube HERITAGE CLAIMS

1994

Nutrini launched

- 27 years of clinical experience in pediatric nutritional support *
- Nutrini is the first pediatric tube feed range introduced in the EU
- First to introduce a tube feed for children with disease related malnutrition in the EU



2003

NutriniMax/Tentrini launched

- NutriniMax/Tentrini is launched - the first age-adapted paediatric tube feed range **



2005

Nutrini Low Energy Multi Fibre launched

- The 1st low energy tube feed for tube fed children with low energy requirements**
- 16 years of knowledge in low energy feeds with fibre for tube fed children



2018

OpTri launched

- New OpTri packaging for tube feeds launched, designed to improve safety, hygiene, user experience & reduced environmental impact



* Launched in EU 1994

** Check local context

Peptisorb range HERITAGE CLAIMS

1998

Nutricia´s 1st publication with Pepti*

- 23 years of research in hydrolysed proteins

2008

Nutrini Peptisorb launched

- Nutrini Peptisorb, the 1st hydrolysed liquid feed for the dietary management of tube fed children with feeding intolerance
- 13 years of experience in hydrolysed liquid feeds for tube fed children with feeding intolerance
- 13 years supporting feeding tolerance in tube fed children



2012

Infatrini Peptisorb launched

- Approaching 10 years *(in 2022)* of supporting infants with feeding tolerance issues
- Nearly a decade use of Infatrini Peptisorb



2017

Nutrini Peptisorb Energy launched

- 5 years of supporting tube fed children with high energy requirements & tolerance issues



* Decsi, T et al., JPGN 1998 27:12-16

** 1998 First Pepti publication, but not FG

UX & SUSTAINABILITY CLAIMS



UX CLAIMS: SENSORY, OPTRI BOTTLE, SUSTAINABILITY