Case Study Booklet

- ✓ Excellent compliance[1]
- ✓ Excellent GI* tolerance[1]
- ✓ Easy to use, convenient and well accepted[1]

NUTRICIA

Nutrini Peptisorb

FOR HEALTHCARE PROFESSIONALS ONLY

* Gastrointestinal

Contents

Introduction

Nutrini Peptisorb Energy Case Studies

- An evaluation of the tolerance, compliance and acceptability of Nutrini Peptisorb Energy was completed over 4 weeks in the United Kingdom. Seven children from the community and hospital, with chronic and complex diseases, who required a high energy peptide based enteral feed were monitored over this period. Dietitians and families collected outcome data on gastrointestinal tolerance, compliance, acceptability, nutrient intake and growth.
- The children ranged from the ages of 1 year 6 months to 14 years 11 months and all had complex medical histories and significant tolerance issues with feeding.
- Despite considerable medical and nutritional challenges, this group of children tolerated the new feed very well, had excellent compliance and maintained or improved their overall nutritional status.
- This booklet contains a summary of the data that was collected during this evaluation followed by a selection of more detailed case studies from 4 of the children.

Summary of Case Studies

Case study	Age	Primary Conditions	Indication for 1.5kcal/ml peptide-based feed	Time on Nutrini Peptisorb Energy	Feeding route and prescription	Results on Nutrini Peptisorb Energy			
						Δ weight	Δ height/ length	Mean compliance	Overall GI tolerance
1	1 year 9 months	Hypoplastic left heart syndrome, heart failure, gastric reflux, oedema	Poor tolerance and absorption of previous feeds, poor growth	4 weeks	NG tube 645kcal/day*	No change	+1.8cm	100%	Improved
2	2 years 5 months	Histiocytic sarcoma, pleural effusion	Poor tolerance to previous 1.5kcal/ml peptide-based feed, dramatic weight loss	4 weeks	NG tube 750kcal/day*	+0.4kg	+0.5cm	92%	Improved
3	10 years 5 months	Type IV bowel astresia, intestinal failure, severe malabsorption	Intolerance to whole protein feeds, malabsorption, poor growth	4 weeks	NG tube 750-1500kcal/day*	+0.9kg	+0.1cm	99%	Stable
4	14 years 11 months	Cerebral palsy, spastic quadriplegia, severe gastric reflux	Poor tolerance to previous feeds, poor growth	4 weeks	Mini button gastrostomy ≥1500kcal/day	-0.3kg‡	No change	100%	Stable
5	1 year 6 months	Necrotising enterocolitis (gut resection), short bowel syndrome	Poor tolerance to previous feeds, malabsorption, poor growth, progression to age appropriate feed	4 weeks	Button gastrostomy 405kcal/day*	+0.4kg	+1.5cm	100%	Improved
6	3 years 2 months	Acute lymphoblastic leukaemia, mucositis, oedema	Intolerance to whole protein feeds, poor growth	17 days	NG tube 750kcal/day	+0.36kg	No change	96%	Stable
7	6 years 4 months	Hoyeraal-Hreidarsson syndrome, aplastic anaemia, bone marrow transplant, cytomegalovirus colitis, oesophageal stricture, dysphagia, ulcers	Poor tolerance and intake of previous 1.5kcal/ml peptide-based feed, poor growth	16 days	NG tube 1200kcal/day	+0.2kg	No change	94%	Stable

* In addition to other sources (e.g. oral food intake, other feeds.) †Gastrointestinal ‡ Weight loss in Week 4 secondary to general illness, clinical condition and the need for surgery

Gastrointestinal Case Study

Case study 5 in summary table on pages 2-3

Background

This female child born prematurely, was diagnosed with necrotising enterocolitis necessitating gut resection at 4 weeks of age, and was consequently enterally fed. Due to her **malabsorption secondary to short bowel syndrome**, she had been historically fed with an infant peptide feed.

At the age of 18 months, she was having 710kcal/d of Infatrini Peptisorb (1kcal/ml hydrolysed, Nutricia) via a button gastrostomy, from a combination of continuous overnight feeding and daytime bolus feeds, in addition to some oral food intake. As a result of the short bowel syndrome, she experienced daily moderate/severe diarrhoea and was **therefore fed to toleration rather than full requirements**.

As a result, by 18 months of age, her growth was slowing, dropping away from the 2nd centile, and she was visibly very thin. Her length was just below the 9th centile.

Rationale and use of Nutrini Peptisorb Energy

In view of the ongoing malabsorption, the decision was made to introduce 1.5kcal/ml **Nutrini Peptisorb Energy to provide a higher nutrient intake in a lower volume** and to promote improved growth with a more appropriate feed for the child's age. The child started using Nutrini Peptisorb Energy at 18 months of age, her weight was 7.55kg (2nd centile) and length 73cm (just below 9th centile). Her calculated nutritional requirements were 845kcal/d (113kcal/kg) and 21.8g/d protein.

Due to her low weight the Dietitian initially prescribed 405kcal/d of Nutrini Peptisorb Energy, to be fed via the gastrostomy in 3 x 90ml daytime bolus feeds, while continuing with 440ml of Infatrini Peptisorb (440kcal/d) overnight, on top of a small oral intake of food. The Dietitian's aim was to promote weight gain to 8kg, and increase the Nutrini Peptisorb Energy prescription to meet the child's full requirements over time.

Results

During 4 weeks of receiving Nutrini Peptisorb Energy, there was **a consistent improvement in the child's diarrhoea**, from being described as moderate/severe before starting the feed to mild throughout the month. There was also a substantial improvement in volume and consistency of bowel movements, with no changes in any other gastrointestinal symptoms. The parents also felt that Nutrini Peptisorb Energy was tolerated very well.

On average the child managed 100% of her feed prescription during the 4 weeks after introduction of Nutrini Peptisorb Energy. By 4 weeks, in view of improved weight gain, the Dietitian had increased the prescription of Nutrini Peptisorb Energy to 1065kcal/d, to fully replace the child's previous feed. The child's nutrient intake from oral diet remained the same at this time but overall she had an increase of +135kcal and +4.7g of protein per day whilst consuming the same volume of feed.

After 4 weeks of receiving Nutrini Peptisorb Energy, her weight had increased to 7.95kg (2nd-9th centile) with a twofold increase in the average rate of weight gain (+50g/week before receiving the Nutrini Peptisorb Energy vs. +100g/week after receiving Nutrini Peptisorb Energy), meeting the Dietitian's goal for growth during this time. Length also increased to 74.5cm (9th centile).

Summary

This child had a complex history of gastrointestinal disease with ongoing malabsorption secondary to short bowel syndrome and consequent faltering growth. However, excellent tolerance of Nutrini Peptisorb Energy led to improvements in weight and length, meeting the dietetic goal and allowing the child's prescription of Nutrini Peptisorb Energy to be increased to promote further growth.

> "Since changing onto Nutrini Peptisorb Energy the main result is that the consistency of the patient's stools have improved and weight has increased. Weight has increased nicely ... Now the patient is virtually at 8kg ... on overnight feeds as well, and so we are hopeful of an even greater improvement in growth in the future... We have prevented decline and aim now towards the 9th."
>
> *~ Managing Dietitian, Bristol Home Management Service*

Genetic Bone Marrow Disorder Case Study

Case study 7 in summary table on pages 2-3

Background

A 6 year and 4 month old boy diagnosed with global developmental delay and aplastic anaemia secondary to Hoyeraal-Hreidarsson syndrome, who developed cytomegalovirus colitis, mouth ulceration and oesophageal stricture with dysphagia following a bone marrow transplant, was being managed by the dietetic team. His height had tracked the 0.4th centile with weight below the 0.4th centile until the age of 5 years and 9 months when nasogastric feeding was commenced, as the ongoing effects of his bone marrow transplant rendered him unable to eat and drink. The introduction of nasogastric feeding improved his nutritional status and he achieved an increase in height to the 0.4th-2nd centile, and in weight to the 25th-50th centile. Initially, he received 1350kcal/d (57kcal/kg) Nutrini Energy Multi Fibre (1.5kcal/ml polymeric, Nutricia) as a continuous overnight feeding at 50ml/hr, with an additional two x 200ml bolus feeds daily.

As a result of the **ongoing effects** of the **bone marrow transplant** he was still experiencing **diarrhoea and abdominal discomfort**. Therefore at the age of 6 years and 4 months he was swapped to a 1.5kcal/ml peptide based feed, which provided 1200kcal/d (57kcal/kg) from continuous overnight feeding and additional daytime bolus feeds via nasogastric tube. This feed was also tolerated poorly with ongoing stomach cramps and diarrhoea preventing full volumes being achieved.

Rationale and use of Nutrini Peptisorb Energy

The decision was made to introduce **Nutrini Peptisorb Energy** to try and improve tolerance and thus **support maintenance of nutritional status** during the ongoing illness following **bone marrow transplant**. Nutrini Peptisorb Energy was introduced, at which time the child had a weight of 20.8kg (25th-50th centile) and height of 107cm (0.4th-2nd centile). He was prescribed 1200kcal/d (58kcal/kg) to be fed at 50ml/hr for 8hrs overnight, with 200ml bolus feeds twice daily, via his nasogastric tube.

Results

The child received Nutrini Peptisorb Energy for a period of 16 days, during this time gastrointestinal tolerance was reported to be stable despite the presence of cytomegalovirus colitis which was causing diarrhoea, abdominal pain and vomiting. There were no notable changes in his gastro-intestinal symptoms and the Dietitian and parents felt that **Nutrini Peptisorb Energy was well tolerated**. Mean compliance was 94% of the feed prescription which met the dietitian's expectations. The child was unable to take any food orally because of his ongoing mouth and throat ulceration, oesophageal stricture and dysphagia. After 16 days of receiving Nutrini Peptisorb Energy, there was a slight increase in weight to 21kg (+0.2kg, 25th-50th centile) and no change in height. The dietitian considered this to be a successful maintenance of nutritional status, despite ongoing illness following the child's bone marrow transplant. The parents reported that the feed was tolerated well, taking into account ongoing symptoms, and reported no problems using Nutrini Peptisorb Energy.

- Managing Dietitian, Birmingham Children's Hospital

Summary

This child had a complex medical history with severe treatment side effects which compromised his nutritional intake and growth, however stable gastrointestinal tolerance and high compliance with Nutrini Peptisorb Energy, enabled this child to maintain his nutritional status.

Oncology Case Study

Case study 2 in summary table on pages 2-3

Background

This female child was diagnosed with a **rare form of cancer, histiocytic sarcoma**, at 2 years and 1 month of age. Treatment with **chemotherapy** was commenced, which resulted in **side effects: nausea, vomiting, diarrhoea and weight loss**. At this time the child was an inpatient in a tertiary-care hospital and was prescribed a peptide-based feed via nasogastric tube to help improve gastrointestinal symptoms and nutritional intake. She was initially receiving 700kcal/d of Nutrini Peptisorb (1kcal/ml hydrolysed, Nutricia). She was then discharged home on 500kcal/d of a peptide-based paediatric oral nutrition supplement as oral food intake had increased at the time.

Over the next few months the **situation worsened and her oral food intake declined again** and her weight decreased from the 98th – 99.6th centile to the 50th centile. This faltering growth was exacerbated by the development of pleural effusion and elevated nutritional requirements secondary to her cancer. Therefore, following readmission to her local hospital at 2 years and 4 months of age, she moved on to a higher energy peptide-based feed, receiving 750kcal/d. Oral food intake was encouraged during the day. This feed was not tolerated well due to the ongoing side effects of chemotherapy. At this time she was admitted for further cycles of chemotherapy to a tertiary-care hospital.

> Weight has been maintained whilst receiving Nutrini Peptisorb Energy. Since our involvement with the patient her weight had dropped 4 centiles due to treatment which is why she was changed onto a higher calorie peptide-based feed.
>
> *~ Managing Dietitian, Birmingham Children's Hospital*

Rationale and use of Nutrini Peptisorb Energy

Nutrini Peptisorb Energy was indicated to try to **prevent further weight loss** during the **current chemotherapy cycle**, as an alternative to her current high energy paediatric peptide-based feed which was not well tolerated at this time. This child started receiving Nutrini Peptisorb Energy at 2 years and 5 months of age (weight 13.8kg, 50th centile) and height 93cm (75th centile). Her calculated nutritional requirements were 1118kcal/d (81kcal/kg) and 12.5g/d of protein. She was prescribed 750kcal/d (54kcal/kg) Nutrini Peptisorb Energy to be administered via nasogastric tube at 45ml/hr overnight, in addition to her oral food intake during the day.

Results

During the first week of receiving Nutrini Peptisorb Energy, despite ongoing chemotherapy, **improvements in gastrointestinal tolerance** were reported with a reduction in **vomiting, nausea and abdominal pain**. No other changes were recorded in her other gastrointestinal symptoms at this point. However further improvements were seen, despite intermittent increases in flatulence being reported on some days. From the second week, a reduction in bloating and burping were also reported. The child's parents felt the feed was very well tolerated.

Over the initial 4 weeks **compliance was very high**, with the child receiving **92% of the feed prescription**. Oral food intake decreased slightly due to a reduced appetite, a side effect of the chemotherapy medications, so the dietitian prescribed an additional 150kcal/d oral Maxijul (carbohydrate powder, Nutricia), and an additional 100ml Nutrini Peptisorb Energy bolus feed to be fed via nasogastric tube in the instances where the child ate less than ¼ of her meals. As a result, total nutrient intake was maintained whilst she was receiving her chemotherapy.

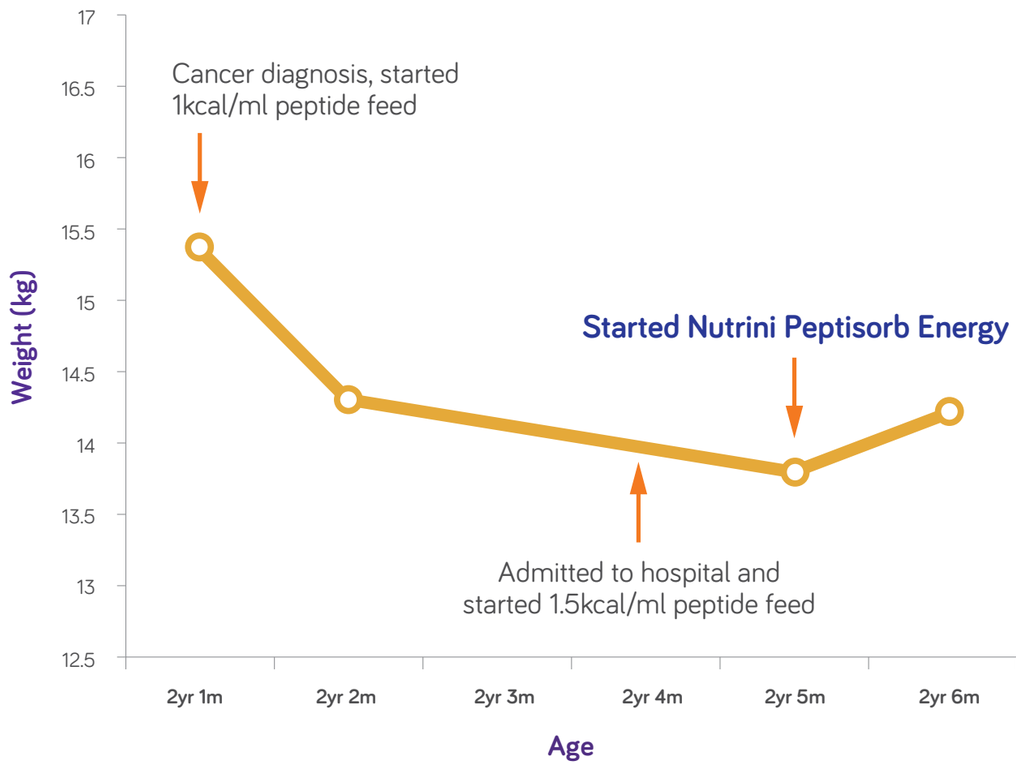
After 4 weeks of receiving Nutrini Peptisorb Energy, the weight loss was attenuated with a slight increase in the child's weight of +0.4kg (14.2kg, 75th-91st centile), (see Figure 1). Height had also increased by +0.5cm to 93.5cm (75th centile).

Summary

Following a cancer diagnosis, this child had experienced a history of dramatic weight loss over 5 months. However, despite the significant side effects of chemotherapy, with an improved gastrointestinal tolerance and good compliance to Nutrini Peptisorb Energy, further weight loss was attenuated with the child beginning to show signs of weight gain.

Her parents reported that Nutrini Peptisorb Energy was equally convenient and as easy to use as the child's previous comparable feed, and were satisfied with the child's tolerance of the feed. She continued to receive Nutrini Peptisorb Energy.

Figure 1: Weight before and after Case Study 2 received Nutrini Peptisorb Energy for 4 weeks



Cardiac Case Study

Case study 1 in summary table on pages 2-3

Background

This child was born at 35/40 weeks with hypoplastic left heart syndrome and had limited oral exposure and development, increased nutritional requirements and gastric reflux. From birth she was unable to meet her nutritional requirements through oral food intake and had been fed via nasogastric tube. At the age of 7 months she was being managed on a mixture of Infatrini (1kcal/ml polymeric, Nutricia) and Duocal (carbohydrate & fat powder, Nutricia) 2% thickened with Instant Carobel (thickening powder, Danone) to help manage gastric reflux via the tube in addition to some oral food intake. At 8 months she was diagnosed as being in heart failure and over the next 5 months her health and cardiac function deteriorated.

Rationale and use of Nutrini Peptisorb Energy

At this point fluid was restricted to 80ml/kg and the child moved onto 645kcal/d of Fortini Multi Fibre (1.5kcal/ml oral supplement, Nutricia) to be taken orally or via nasogastric tube in addition to oral food intake. However, tolerance of this was poor with repeated diarrhoea, bloating and fluid retention (hard abdomen) secondary to poor oxygen perfusion. Dioralyte®™ (electrolyte powder, Sanofi) was given overnight and her oral food intake increased slightly, but **the volume of feed was limited** and she was **failing to meet her nutritional requirements**.

As a result, at 1 year 9 months of age, her weight had decreased to the 25th-50th centile and length to the 2nd centile, there was increasing concern regarding her **faltering growth**. It was at this point the decision was made to introduce **Nutrini Peptisorb Energy**, a more energy dense, peptide-based feed, aiming to improve her feed tolerance and absorption, to try and **help more consistently meet nutritional requirements in a smaller volume** and ultimately to **promote growth**.

This child started using Nutrini Peptisorb Energy, at this point her weight was 10.5kg (25th-50th centile) with significant fluid overload, her length was 77cm (2nd centile) and her head circumference 46cm (25th centile). Her calculated nutritional requirements were 945kcal (90kcal kg) and 11g of protein per day. She was prescribed 645kcal/d (61kcal/kg) Nutrini Peptisorb Energy, fed via 3 x 90ml bolus feeds per day and the remainder given overnight at 16ml/hr via nasogastric tube, in addition to oral food intake.

Results

The child was monitored closely for the first 4 weeks whilst taking Nutrini Peptisorb Energy. She experienced **marked improvements in gastrointestinal tolerance with reduced diarrhoea, flatulence and bloating**. Her parents felt that Nutrini Peptisorb Energy was very well tolerated, and that the child tolerated this better than their previous paediatric feed. **Compliance with feed prescription was excellent** with the child receiving **100% of the feed prescription** throughout the 4 weeks. Oral food intake also improved slightly at week 4 by +95kcal and +1.6g protein per day, so that the child's overall nutrient intake increased. After 4 weeks of receiving Nutrini Peptisorb Energy, growth was maintained. There was visible improvement in fluid retention (soft abdomen), so that the child's weight was slightly lower after 4 weeks on Nutrini Peptisorb Energy (10.24kg, -0.28kg, 25th centile) but "dry weight" was considered stable. Length increased to 78.8cm (+1.8cm, 9th centile), and the dietitian anecdotally reported that the child was growing out of her push chair and trousers. Head circumference remained the same.

> This patient is doing very well overall compared to baseline when she was an inpatient... in herself she seems happy and is about to take her first steps. Oral intake continues to improve significantly which I feel is due to her improved bloating and GI symptoms. There was a significant improvement in diarrhoea, flatulence and bloating from starting Nutrini Peptisorb Energy. Parents were very pleased with the outcome. This patient will be continuing on the feed.
>
> *~ Managing Dietitian, Birmingham Children's Hospital*

Summary

This child, with a history of faltering growth exacerbated by elevated nutritional requirements, malabsorption and poor tolerance to whole protein feeds, made considerable progress during 4 weeks of receiving Nutrini Peptisorb Energy. She was able to be discharged from hospital during this time after improvements in her general condition, including a reduction of fluid retention. The parents reported that Nutrini Peptisorb Energy was very easy to use, convenient, very well tolerated and was preferred to the previous feed. The Dietitian reported that after 4 weeks the child seemed very happy and was about to take her first steps. She continued to receive Nutrini Peptisorb Energy after the 4 week period.

Nutrini Peptisorb: the easy to use[1] peptide-based feed specially formulated for children with tolerance issues

- **100% whey protein** – to aid digestion and tolerance[2] by supporting faster gastric emptying[3-5] and reduce the frequency of reflux.[3,5]
- **Extensively hydrolysed** – with >75% of peptides being <1000Da to optimise nutrient absorption and comfort in children with tolerance issues.[6]
- **Optimal balance of fats** – a mix of medium-chain triglycerides (MCT) and long-chain triglycerides (LCT) to help promote absorption and tolerance.[7,8]
- **Available in 2 energy densities** – 1kcal/ml and 1.5kcal/ml, providing more nutrition in a smaller volume for children with high energy and/or low fluid needs.
- **Easy to use** – ready to feed with a 24 hour hang time, providing convenience and a reduced risk of contamination and preparation error.[1]

Nutrini Peptisorb

the easy to use[1] peptide-based feed delivering relief to children with tolerance issues

Nutrini Peptisorb 1.0kcal/ml

PBS Listed

Nutrini Peptisorb Energy 1.5kcal/ml

	Nutrini Peptisorb	Nutrini Peptisorb Energy
Age range	1+ years (8-20kg)	1+ years (or 8-45kg)
Energy	1kcal/ml	1.5kcal/ml
Nutritionally complete	Yes	Yes
100% whey protein	Yes	Yes
% peptides <1000Da	>80%	>75%
Protein, per 100ml	2.8g	4.2g
MCT, % total fat	46%	51%
Contains DHA and EPA	No	Yes
Contains Fibre	No	Yes (<0.5g per 100ml)
Osmolality, mOsmol/kg H_2O	345	510
Carton Size	8 x 500ml pack	12 x 500ml OpTri bottle
PBS Prescribing Code	10375C	11939J

Available for home delivery through Nutricia at Home Pharmacy, register at **nutriciaathome.com.au**

References: **1.** Data on file, 2017. Nutricia Ltd, UK. **2.** Alexander DD *et al.* World J Gastrointest Pharmacol Ther. 2016; 7(2): 306-19. **3.** Fried MD *et al.* J Pediatr 1992; 120(4.1): 569-72. **4.** Khoshoo V *et al.* Eur J Clin Nutr. 2002; 56(7): 656- 8. **5.** Meyer R *et al.* BMC Gastroenterol. 2015; 15: 137. **6.** Khoshoo V *et al.* 1996 22(1): 48-55. **7.** Bach AC *et al.* Am J Clin Nutr 1982; 36: 950–62. **8.** Goulet O *et al.* Journal of Pediatric Gastroenterology & Nutrition 2004; 38(3): 250-269.

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