

# Minor reformulations of infant food for special medical purposes due to EU regulations 2016/127 & 2016/128 are well tolerated, accepted, complied with and continue to support growth in infants and children requiring nutrition support for the management of

## various clinical conditions

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### INTRODUCTION

The nutritional compositions of infant foods for special medical purposes (iFSMPs) are governed by the EU, and new regulations (2016/127; 2016/128) were implemented to ensure standardisation and implementation of the latest nutritional recommendations, scheduled to take effect by February 2020. Amongst the changes required, nutrient minimum and maximum levels were redefined, as well as mandatory supplementation of docosahexaenoic acid (DHA).

Anecdotal evidence from clinical practice suggests that changes to formulations, minor or otherwise, may affect tolerance and acceptance in infants taking iFSMPs, especially those with complex medical conditions and backgrounds.

### AIM

A multi-centre case study series in 17 UK paediatric centres was conducted to evaluate iFSMPs reformulated by Nutricia Ltd to understand any possible impact on infants and children prescribed such iFSMPs for a range of clinical conditions. Gastrointestinal tolerance, acceptance and compliance were evaluated over 28 days in each case study.

### METHODS

From the UK paediatric centres, 44 infants and children were recruited [mean age 16.5m; range 1.5-87], receiving one of the iFSMPs described in Table 1, prescribed for nutrition support relevant to their clinical condition and/or indication.

Medical history was recorded at baseline, and growth, gastrointestinal (GI) tolerance, compliance and acceptance was measured at baseline and end of case study. The managing Dietitian determined prescribed daily volume of the reformulated iFSMP (relevant to their clinical condition/indication) for each patient during the case study.

**Table 1. Number of patients and clinical condition/indication per iFSMP prescribed**

Number (n) of patients per iFSMP	Clinical condition/indication
Infatrini (n=9)	Faltering growth
Infatrini Peptisorb (n=3)	GI Intolerance
Neocate LCP (n=9)	Cow's milk allergy (n=8) Severe GI intolerance (n=1)
Neocate Syneo (n=1)	Cow's milk allergy
Kindergen (n=4)	Chronic renal disease
Monogen (n=5)	Chylothorax
Energivit (n=4)	Restricted protein diet
Locasol (n=4)	Restricted calcium intake
Galactomin 19 (n=1)	Glucose-galactose malabsorption
PKU Anamix Infant (n=4)	Phenylketonuria (PKU)

### RESULTS

Forty patients completed the 28-day evaluation (n=4 were unable to complete due to medical and/or other reasons; range of days on case study 1-17).

Mean intake of baseline iFSMPs was 683±275ml (which met 97% of prescribed daily volume), of which n=16 patients

administered iFSMPs via enteral feeding tubes.

GI tolerance remained stable in the majority of case studies (n=41 including n=1 drop out), and any deviations were not attributed to the reformulated iFSMPs.

For patients that completed the 28-day evaluation, compliance remained stable (n=33), and any reduction was related to increased complementary feeding or medical reasons. Mean intake of reformulated iFSMPs was 579±254ml (which met 91% of prescribed daily volume), where the majority of patients directly transitioned onto the reformulation (n=41).

No deterioration in medical conditions or growth were reported as a result of using the reformulated iFSMPs during any of the case studies. Furthermore, caregiver and HCP satisfaction was positively recorded in 89% of case studies.

### CONCLUSION

This multi-centre, case study series demonstrates that the minor reformulation of iFSMPs manufactured by Nutricia Ltd in line with the Commission Delegated Regulations (2016/127; 2016/128) to amend nutrient levels and include DHA are well tolerated, accepted and complied with in infants and children with various medical backgrounds.

Furthermore, the reformulated iFSMPs continued to support growth and achieved positive caregiver and HCP satisfaction which is paramount to patient care.

The reformulated iFSMPs used in this case study series have since been implemented into clinical practice in the UK, with support from Nutricia Ltd, and are now widely accepted.