April 2020

Dear Healthcare Professional,

RE: Minor reformulation to Low Fat Module due to updated EU Regulations

Low Fat Module is a powdered product containing cow's milk protein, carbohydrate, vitamins, minerals and trace elements for the dietary management of infants and children with disorders of fat metabolism e.g. fat maldigestion and/or malabsorption, chylothorax, disorders of fatty acid oxidation such as medium chain acyl-CoA dehydrogenase deficiency (MCADD) and long chain fatty acid oxidation disorders such as defects of β-oxidation. Low Fat Module is a Food for Special Medical Purposes (FSMP) for use under medical supervision for infants and children.

FSMPs intended for infants are required to be updated in line with new EU Regulations (2016/127; 2016/128) by 22nd February 2020, as communicated in a letter sent in June 2019. Nutricia is working to ensure compliance for all infant feeds by this deadline. To see a full list of feeds that will be updated, please visit our website: https://www.nutriciahcp.com/adult/Studies/Infant_FSMP_EU_Regulation_Updates/

The formulation of Low Fat Module has been updated to meet the requirements of the new regulations, including adjusted levels of some micronutrients. We have also taken the opportunity with this formulation update to upgrade the formulations in line with up-to-date guidelines. The minor changes and rationale for change are presented in Appendix 1 and 2 of this letter.

We have done our best to limit changes to the formulations where possible, to minimise any impact on you or your patients. However, with these mandatory changes your patients may notice a slight difference in smell, appearance and/or taste of the formulation.

Due to the regulatory requirements there may also be changes to the product label; parents may look to healthcare professionals for reassurance, so it's important that you are aware of the changes to support parents.

We anticipate that the updated formulation of Low Fat Module will be available from approximately June 2020 in the UK and in Ireland, dependent on fluctuations in the supply chain. There will be a gradual change over of new and existing product in the market, the PIP codes will not change. Please therefore anticipate that new and existing patients may receive the updated formulation of Low Fat Module from the date outlined above; please review the formulation updates in Appendix 1 and 2 on receiving this letter and ahead of the date of introduction to ensure a smooth transition for your patients.

Tins of the updated formulation will be identifiable by a sticker on the lid of each tin, and a slightly different appearance of the label. An example of the sticker and the new tin label is included in Appendix 3.

Nutricia is committed to being compliant with the new regulation by the required deadline. You may therefore notice updated infant feed products from the Nutricia range on the market from the beginning of 2020 through to the end of 2020, allowing for differences in production schedules and sell through of existing stock. You may also receive other product-specific communications of a similar nature over the coming months.

As ever Nutricia will continue to supply the best quality products to help you manage the nutritional needs of your patients. If you have any further questions, please contact us at resourcecentre@nutricia.com.

In our best efforts to ensure this and future communications on this subject reach all relevant Healthcare Professionals, we apologise if you receive this information more than once.

Yours faithfully,

Heidi Chan
Senior Medical Affairs Manager

Appendix 1: Low Fat Module Current and Updated Formulation Comparison Table

AVERAGE CONTENTS		Updated		Current	
		per 100g	**per 100ml***	**per 100g**	**per 100ml****
Energy:	kcal kJ	381 1615	55 233	374 1589	67 286
Protein:	g	13.9	2.0	8.7	1.6
Energy	%	*14.9*	*14.9*	*9*	*9*
Carbohydrate:	g	80.1	11.5	83	14.9
sugars	g	39.9	5.7	8.3	1.5
lactose	g	38.2	5.5	0.9	0.16
Energy	%	*83.9*	*83.9*	*89*	*89*
Fat:	g	0.65	0.09	0.8	0.14
saturates	g	0.48	0.07	0.54	0.10
monounsaturates	g	0.13	0.02	0.2	0.04
polyunsaturates	g	0.04	0.01	0.02	0.004
linoleic acid	mg	40	5.16	13.8	2.5
α-linoleic acid	mg	3.5	0.49	4.0	0.72
Fibre	g	0	0	0	0
Energy	%	*0*	*0*	*0*	*0*
Minerals:					
sodium	mg (mmol)	157 (6.84)	22.7 (0.99)	90 (3.9)	16.2 (0.7)
potassium	mg (mmol)	420 (10.7)	60.4 (1.55)	315 (8.1)	56.7 (1.5)
chloride	mg (mmol)	254 (7.18)	35.6 (1.03)	218 (6.2)	39.2 (1.1)
calcium	mg (mmol)	442 (11)	63.6 (1.59)	244 (6.1)	44 (1.1)
phosphorus	mg (mmol PO_4)	272 (8.79)	39.2 (1.27)	173 (5.6)	31 (1.0)
magnesium	mg (mmol)	37 (1.52)	5.33 (0.22)	26 (1.1)	4.6 (0.19)
iron	mg	6.98	1.01	5.3	0.95
copper	mg	0.36	0.051	0.34	0.06
zinc	mg	3.64	0.52	3.75	0.68
manganese	mg	0.039	0.006	0.33	0.06
iodine	µg	62.5	9.00	40	7.2
molybdenum	µg	22.1	3.19	11.4	2.1
selenium	µg	12.5	1.80	8.2	1.5
chromium	µg	12.7	1.83	8.0	1.4
Vitamins:					
vitamin A	µg	485	69.9	396	71.3
vitamin D	µg	8.79	1.27	6.4	1.2
vitamin E	mg (α-TE)	5.54 (7.5)	0.80 (1.08)	2.3	0.4
vitamin C	mg	57.3	8.25	45	8.1
vitamin K	µg	20.8	3.00	15.8	2.8
thiamin	mg	0.41	0.06	0.29	0.05
riboflavin	mg	0.71	0.10	0.45	0.08
niacin	mg (mg NE)	4.16 (7.96)	0.60 (1.15)	3.4 (6.4)	0.6 (1.5)
vitamin B_6	mg	0.32	0.05	0.39	0.07
folic acid	µg	52.0	7.49	28.5	5.1
pantothenic acid	mg	2.40	0.35	2.0	0.36
vitamin B_{12}	µg	1.18	0.17	0.94	0.17
biotin	µg	13.6	1.95	19.5	3.5
Others:					
L-carnitine	mg	6.62	0.95	9	1.6
choline	mg	84.4	12.1	37.5	6.8
inositol	mg	90.1	13.0	75	13.5
taurine	mg	6.25	0.90	24	4.3
Water:					
osmolality*	mOsmol/kgH_2O	-	279	-	270
Fatty Acid Profile		**per 100g fatty acid**		**per 100g fatty acid**	
Butyric acid ($C_{4:0}$)	g	2.79	2.45	3.64	-
Caproic acid ($C_{6:0}$)	g	1.86	1.64	2.34	-
Caprylic acid ($C_{8:0}$)	g	1.30	1.15	1.3	-
Capric acid ($C_{10:0}$)	g	2.79	2.45	2.9	-
Lauric acid ($C_{12:0}$)	g	4.19	3.68	3.9	-
Myristic acid ($C_{14:0}$)	g	11.2	9.82	10.7	-
Palmitic acid ($C_{16:0}$)	g	29.5	25.9	30.3	-
Palmitoleic acid ($C_{16:1}$)	g	1.68	1.47	1.8	-
Stearic acid ($C_{18:0}$)	g	9.45	8.31	11.7	-
Oleic acid ($C_{18:1}$)	g	23.1	20.3	21.9	-
Linoleic acid ($C_{18:2}$)	g	5.87	5.16	1.82	-
Alpha linolenic acid ($C_{18:3}$)	g	0.56	0.49	0.52	-
Arachidic acid ($C_{20:0}$)	g	0.19	0.16	-	-
Eicosaenoic acid ($C_{20:1}$)	g	0.09	0.08	0.26	-
Other long chain fatty acids	g	5.40	4.75	-	-

* At the recommended dilution 14.4% w/v

** At the recommended dilution 18% w/v

Appendix 2: Low Fat Module key updates, including those as a result of Regulations 2016/127; 2016/128.

Manganese

The level of manganese within Low Fat Module has been updated to 0.039mg/100g. This decrease in manganese has been implemented to be in line with the updated EFSA Scientific Opinion on Dietary Reference Values for manganese[1].

Carbohydrate and lactose

The level of lactose has been updated to 38.2g/100g due to the change in ingredient blend. This is no longer suitable for low lactose indication.

Fatty acids

The level of LA within Low Fat Module has been updated to 40mg/100g and level of ALA has been updated to 3.5mg/100g, due to alignment with the new EU FSMP Regulation.

Scoop change

The scoop inside the tin has changed to ensure the correct product dosing. It has changed to a dark blue scoop with 10.5ml volume or 4.8g weight.

Other properties

The reformulated product has a higher density and will now be available in a 300g tin. It will have an extended shelf life of 18 months.

[1]EFSA Panel on Dietetic Products, Nutrition and Allergies. Scientific Opinion on Dietary Reference Values for manganese. EFSA Journal. 2013;11(11:3419):1-44

Appendix 3: Low Fat Module sticker example on the formulated tin