

April 2020

Dear Healthcare Professional,

RE: Minor reformulation to Locasol due to updated EU Regulations

Locasol, is a powdered feed containing cows' milk protein, carbohydrate, fat, vitamins, minerals and trace elements with a very low calcium and no vitamin D content. Locasol is designed for use in the dietary management of those conditions where an extreme restriction of calcium and vitamin D is required e.g. hypercalcaemia. Locasol is a Food for Special Medical Purposes (FSMP) for use under medical supervision from 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 Locasol 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.

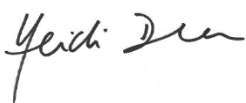
We anticipate that the updated formulation of Locasol will be available from approximately June 2020 in the UK and in Ireland, dependent on fluctuations in the supply chain. There will be a gradual change over of new and existing product in the market, the PIP codes will not change. Please therefore anticipate that new and existing patients may receive the updated formulation of Locasol 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 throughout 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: Locasol Current and Updated Formulation Comparison Table

AVERAGE CONTENTS		Updated		Current	
		per 100g	per 100ml*	per 100g	per 100ml**
Energy:	kcal	512	66	508	66
	kJ	2144	277	2125	278
Protein:	g	14.8	1.9	14.6	1.9
<i>Energy</i>	%	11.6		11.5	
Carbohydrate:	g	55.2	7.1	53.7	7.0
sugars	g	54.8	7.1	52.5	6.9
lactose	g	54.8	7.06	52.4	6.9
<i>Energy</i>	%	43.1		42.3	
Fat:	g	25.8	3.3	26.1	3.4
saturates	g	9.8	1.3	9.2	1.2
monounsaturates	g	12.9	1.7	12.6	1.7
polyunsaturates	g	3.2	0.41	3.1	0.41
n6:n3	ratio	5.76			
<i>Energy</i>	%	45.3		46.2	
Fibre	g	0	0	0	0
<i>Energy</i>	%	0		0	
Minerals:					
sodium	mg (mmol)	227 (9.89)	29.3 (1.28)	219 (9.5)	28.7 (1.2)
potassium	mg (mmol)	466 (11.9)	60.1 (1.54)	640 (16.4)	83.8 (2.1)
chloride	mg (mmol)	310 (8.75)	40.0 (1.13)	460 (13.0)	60.3 (1.7)
calcium	mg (mmol)	<29.1 (<0.73)	<3.75 (<0.09)	<55 (<5)	<7.0 (<0.5)
phosphorus	mg (mmol)	172 (5.54)	22.1 (0.71)	350 (11.3)	46 (1.5)
magnesium	mg (mmol)	42.7 (1.75)	5.50 (0.23)	50.0 (2.1)	6.6 (0.27)
iron	mg	7.78	1.00	4.0	0.52
copper	mg	0.39	0.05	0.31	0.04
zinc	mg	3.89	0.50	3.0	0.39
manganese	mg	0.051	0.007	0.40	0.05
iodine	µg	69.6	8.98	78.0	10
molybdenum	µg	19.5	2.51	35.0	4.6
selenium	µg	12.4	1.60	11.5	1.5
chromium	µg	15.4	1.98	30.0	3.9
Vitamins:					
vitamin A	µg	584	75.3	600	78.6
vitamin D	µg	-	-	-	-
vitamin E	mg (mg-TE)	9.06 (10.1)	1.17 (1.30)	7.4 mg-α-TE	0.97 mg-α-TE
vitamin C	mg	69.6	8.98	60.0	7.9
vitamin K	µg	25.3	3.26	40.0	5.2
thiamin	mg	0.46	0.06	0.30	0.04
riboflavin	mg	0.77	0.10	0.80	0.10
niacin	mg (mg NE)	4.66 (8.14)	0.60 (1.05)	4.5 (7.8)	0.59 (1.0)
vitamin B ₆	mg	0.30	0.04	0.30	0.04
folic acid	µg	54.3	7.00	80.0	10.5
pantothenic acid	mg	2.71	0.35	2.1	0.28
vitamin B ₁₂	µg	0.97	0.13	1.5	0.20
biotin	µg	14.0	1.80	12.0	1.6
Others:					
L-carnitine	mg	30.2	3.90	6.9	0.90
choline	mg	90.6	11.7	50.0	6.5
inositol	mg	25.6	3.30	25.0	3.3
taurine	mg	6.96	0.90	29.5	3.9
Water:					
osmolality	mOsmol/kgH ₂ O	310	310	310	310
Fatty Acid Profile					
Butyric acid (C _{4:0})	g/100g fatty acids		0.03		0.05
Caproic acid (C _{6:0})	g/100g fatty acids		0.14		0.10
Caprylic acid (C _{8:0})	g/100g fatty acids		1.44		1.3
Capric acid (C _{10:0})	g/100g fatty acids		1.10		1.1
Lauric acid (C _{12:0})	g/100g fatty acids		8.43		8.3
Myristic acid (C _{14:0})	g/100g fatty acids		3.60		3.8
Palmitic acid (C _{16:0})	g/100g fatty acids		17.9		18.1
Stearic acid (C _{18:0})	g/100g fatty acids		3.21		3.6
Oleic acid (C _{18:1})	g/100g fatty acids		49.1		49.3
Linoleic acid (C _{18:2})	g/100g fatty acids		10.4		10.6
Alpha linolenic acid (C _{18:3})	g/100g fatty acids		1.81		1.95
Arachidonic acid (C _{20:4})	g/100g fatty acids		-		-
Docosahaexanoic acid (C _{22:6})	g/100g fatty acids		-		-
Other long chain fatty acids	g/100g fatty acids		1.24		0.50

* Prepared per 100ml with 12.9g powder

** Prepared per 100ml with 13.2g powder

Appendix 2: Locasol key formulation updates other than those as a result of Regulations 2016/127; 2016/128.

Manganese

The level of manganese within Locasol has been updated to 0.051mg/100g. This decrease in manganese has been implemented to be in line with the updated EFSA Scientific Opinion on Dietary Reference Values for manganese¹.

Calcium

The level of calcium within Locasol has been updated to <29.1mg /100g.

Iron

The level of iron within Locasol has been updated to 7.78mg /100g.

Carbohydrate and lactose

The level of lactose within Locasol has been updated to 54.8g /100g due to a change in ingredient blend.

Folic acid

The level of folic acid within Locasol has been updated to 54.3µg /100g.

Soy

Presence of soy as an allergen is a result of the soy lecithin (E322) present in the coconut oil.

Nutritionally incomplete

The product is considered nutritionally incomplete due to the absence of Vitamin D and DHA, and changes in micronutrients. Due to the specialist nature of Locasol, the clinical use should continue to be dictated by your clinical assessment of the patient in your care.

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Scoop size

The scoop inside the tin will now provide 4.3g powder

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

