



April 2023

## UCD Anamix Infant Formula Now Available in the United States

Dear Metabolic Healthcare Professionals,

Earlier this year, we communicated our steadfast commitment to the metabolic community and focus on our medical formula business. As last year's global infant formula crisis and supply challenges impacted the rare metabolic community, Nutricia worked diligently with the FDA to bring specialty formulas to the United States. We secured an uninterrupted supply of metabolic infant formulas throughout the entire formula crisis. As we look forward to servicing both current and new babies with our best-in-class *Periflex*<sup>®</sup>/*Anamix*<sup>®</sup> *Early Years* infant formulas, we are pleased to share a new addition to our infant portfolio.

It is with great pride that we announce the availability of **UCD Anamix<sup>®</sup> Infant** in the United States.

**UCD Anamix Infant** is a metabolic infant formula for infants diagnosed with a urea cycle disorder (UCD). The formula has been a trusted UCD metabolic infant formula in many countries for years. We have an ample supply of sample cans, available through your Nutricia sales representative, to help any newborn UCD infants get started. We will have additional supply available through traditional channels in the coming weeks.

**UCD Anamix Infant** is being imported under FDA's discretionary enforcement period with European labels listing information in English and Spanish.

To help us plan even better for the future, it would be helpful to get more information about your center's UCD metabolic infant formula needs. Our sales representatives will be reaching out to discuss your clinic's specific needs for UCD infant formula.

In the meantime, for more information about **UCD Anamix Infant**, please see below information or contact your sales representative. Our Medical Affairs team is also available to answer any technical questions and can be reached via email at [NutritionServices@nutricia.com](mailto:NutritionServices@nutricia.com) or by calling 1-800-365-7354 (Mo-Fr 8:30 am – 5:00 pm ET).

Sincerely,

Your Nutricia Metabolics Team



# UCD ANAMIX<sup>®</sup> INFANT

An amino acid-based powdered infant formula with iron containing essential amino acids (with increased levels of branched-chain amino acids (BCAA)), carbohydrate, fat (including DHA and ARA), vitamins, minerals and trace elements.

For the dietary management of urea cycle disorders (UCD), hyperammonemia-hyperornithinemia-homocitrullinuria (HHH) syndrome and gyrate atrophy in infants.

**UCD Anamix Infant** is available under FDA enforcement discretion and so is imported with European label in English and Spanish.



**Indication:** Urea cycle disorders (UCD), hyperammonemia-hyperornithinemia-homocitrullinuria (HHH) syndrome and gyrate atrophy

## Nutrition Information:

Nutrients	Per 100 g of powder	Per 10 g Protein Equivalent
<b>Calories</b>	<b>492</b>	<b>656</b>
<b>Protein Equivalent, g</b>	<b>7.5</b>	<b>10.0</b>
<b>Fat, g</b>	<b>26.4</b>	<b>35.2</b>
Saturated, g	10.4	13.9
Monounsaturated, g	11.7	15.6
Polyunsaturated, g	4.3	5.7
DHA, mg	130	173
ARA, mg	130	173
Linoleic Acid, mg	3.44	4.6
<b>Carbohydrate, g</b>	<b>56.5</b>	<b>75.3</b>
Fiber	0	0
<b>Amino Acids, g</b>		
L-Alanine	-	-
L-Arginine	-	-
L-Aspartic Acid	-	-
L-Cystine	0.27	0.36
L-Glutamine	-	-
Glycine	-	-
L-Histidine	0.32	0.43
L-Isoleucine	1.40	1.87
L-Leucine	2.40	3.20
L-Lysine	1.20	1.60
L-Methionine	0.25	0.33
L-Phenylalanine	0.42	0.56
L-Proline	-	-
L-Serine	-	-
L-Threonine	0.99	1.32
L-Tryptophan	0.30	0.40
L-Tyrosine	0.77	1.03
L-Valine	1.40	1.87
L-Carnitine	0.01	0.01
Taurine	0.04	0.05

Vitamins	Per 100 g of powder	Per 10 g Protein Equivalent
Vitamin A, IU (mcg RE)	1435 (431)	1914 (575)
Vitamin D <sub>3</sub> , IU (mcg)	472 (11.8)	629 (15.7)
Vitamin E, IU (mg α-TE)	17.5 (11.7)	23.3 (15.6)
Vitamin K, mcg	40.0	53.3
Thiamine, mcg	540	720
Riboflavin, mcg	540	720
Vitamin B <sub>6</sub> , mcg	540	720
Vitamin B <sub>12</sub> , mcg	1.3	1.7
Niacin, mcg	2500	3333
Folic Acid, mcg	58.1	77.5
Pantothenic Acid, mcg	3000	4000
Biotin, mcg	19.3	25.7
Vitamin C, mg	51.5	68.7
Choline, mg	154	205
Inositol, mg	104	139
<b>Minerals</b>		
Calcium, mg	670	893
Phosphorus, mg	442	589
Magnesium, mcg	73.0	97.3
Iron, mg	8.7	11.6
Zinc, mg	6.1	8.1
Manganese, mcg	31.0	41.3
Copper, mcg	450	600
Iodine, mcg	99.4	133
Molybdenum, mcg	12.9	17.2
Chromium, mcg	14.8	19.7
Selenium, mcg	18.7	24.9
Sodium, mg	295	393
Potassium, mg	713	951
Chloride, mg	530	707

# Ordering/Reimbursement Information for UCD Anamix® Infant:

Product Code	Reimbursement Code	HCPSC Code*†	Product Packaging	Calories Per Can
146539	49735-0155-51	B4162	6 x 400 g (14.1 oz)	1968

†Submitted  
\* S9435 = For individuals who submit their bills to insurance on their own.

## Ingredients:

Glucose Syrup, Vegetable Oils (High Oleic Sunflower Oil, Coconut Oil, Rapeseed Oil, Sunflower Oil), L-Leucine, Potassium Citrate, Calcium Phosphate, L-Lysine Hydrochloride, L-Valine, L-Isoleucine, Citric Acid Esters Of Mono- And Diglycerides Of Fatty Acids, L-Threonine, L-Tyrosine, Magnesium Acetate, Choline Bitartrate, Sodium Chloride, L-Phenylalanine, Sodium Hydrogen Phosphate, Calcium Glycerophosphate, L-Histidine, L-Tryptophan, Oil From *Cryptocodinium Cohnii*\*\*, L-Cystine, L-Methionine, Oil From *Mortierella Alpina*††, Sucrose, Inositol, L-Ascorbic Acid, Antioxidants (Sunflower Lecithin, Ascorbyl Palmitate), Taurine, Ferrous Sulphate, Zinc Sulphate, L-Carnitine, DL-Alpha Tocopheryl Acetate, Calcium D-Pantothenate, Nicotinamide, Copper Sulphate, Thiamin Hydrochloride, Pyridoxine Hydrochloride, Riboflavin, Retinyl Acetate, Potassium Iodide, Manganese Sulphate, Pteroylmonoglutamic Acid, Chromium Chloride, Phytomenadione, Sodium Selenite, Sodium Molybdate, D-Biotin, Cholecalciferol, Cyanocobalamin.

\*\* A source of Docosahexaenoic Acid (DHA)  
†† A source of Arachidonic Acid (ARA)

## Suggested Intake:

The quantity of formula and the dilution should be determined by a qualified healthcare professional only and is dependent on the age, body weight and medical condition of the patient.

## Directions for Preparation and Use:

- To make the recommended dilution, add 1 unpacked level scoop (5 g) of powder to each fluid ounce of water (30 mL). Only use the scoop provided. For accuracy, formula should be weighed on a gram scale.



**THE HEALTH OF YOUR INFANT DEPENDS ON CAREFULLY FOLLOWING THE DIRECTIONS FOR PREPARATION AND USE. INCORRECT PREPARATION CAN MAKE YOUR BABY ILL.**

### To make formula:

- Wash hands thoroughly and clean the preparation area
- Boil fresh water for 5 minutes. Cool for at least 30 minutes so that it feels warm to the wrist. Pour the required amount of water into a sterilized feeding bottle.
- Fill the scoop provided with powder and level off with a clean, dry knife. Do not press the powder into the scoop. Only use the scoop provided.
- Add the prescribed number of scoops of powder to the water. Replace the cap on the bottle and shake until the powder dissolves. Before feeding, ensure that the formula is at the correct temperature by placing a few drops on the wrist.

- Use immediately after reconstitution. Any prepared product remaining in the bottle after one hour of feeding should be discarded. The prepared product must not be rewarmed during feeding.

## Important Preparation Information:

Powdered product is not sterile. Prepare the formula immediately prior to use. Do not boil and do not use a microwave oven to heat the formula.

## Storage:

Store unopened cans in a cool, dry place. Always replace container lid after use. Avoid extreme temperatures. Once opened, use contents within 2 weeks.

## Important Notice:

Must only be used under medical supervision. For oral and tube feeding. Not for parenteral use. Not suitable as a sole source of nutrition. Must be given in conjunction with an intact protein source e.g. breast milk or infant formula to supply the fluid and general nutritional requirements of the patient in quantities as prescribed by a healthcare professional. Only suitable for infants with proven urea cycle disorders (UCD), hyperammonemia-hyperornithinemia-homocitrullinuria (HHH) syndrome and gyrate atrophy.

Amount of Water	Amount of UCD Anamix Infant Powder to Add	Approximate Protein Equivalent	Approximate Final Volume
3 fl oz (90 mL)	15 g (approx. 3 scoops)	11 g	3.4 fl oz (100 mL)
Osmolality at this concentration is 310 mOsmol/kg H <sub>2</sub> O.			

