



# SpectrumNeeds<sup>™</sup>, a New Comprehensive Nutritional Therapy for Autism, Functional Conditions, and Mitochondrial Disease

Richard G. Boles, M.D. Chief Medical & Scientific Officer NeuroNeeds LLC Director, CNNH NeuroGenomics Program [telemedicine] Medical Geneticist in Private Practice Faculty Advisor, MitoAction MitoAction Webinar April 6, 2018





Disclosure: Dr. Boles wears many hats









- Chief Medical & Scientific Officer of NeuroNeeds LLC
  - Present: The company that produces SpectrumNeeds™ (https://neuroneeds.com)
- Medical Director for DNA Sequencing Companies
  - Past: 5 years at Courtagen Life Sciences; 6 months at Lineagen
  - Present: Loose affiliations with some companies
  - Roles: Test development, testing, interpretation, marketing
- Researcher with prior NIH and foundation funding
  - Past: USC faculty for 20 years
  - Present: Study sequence variation that predispose towards neurodevelopmental and functional disorders
- Clinician treating patients
  - Primary interests in functional disease (autism, cyclic vomiting)
  - Past: Geneticist/pediatrician 20 years at CHLA/USC
  - Present: In private practice since 2014 (http://molecularmitomd.com)
  - Present: Telemedicine as part of CNNH NeuroGenomics Program (https://cnnh.org)



- What does the medical literature say regarding the uses of nutritional therapies in the autism and related neurodevelopmental disorders?
- What about the uses of nutritional therapies in functional disease such as pain, fatigue, GI dysmotility, dysautonomia, anxiety, and depression?
- What exactly is SpectrumNeeds<sup>™</sup>, and how can it be used as nutritional support for the above conditions?
- SpectrumNeeds<sup>™</sup> beyond the spectrum: What about the use of this product in the average "mito" patient?
- How to integrate SpectrumNeeds<sup>™</sup> into a complicated supplement regiment.



## **Metabolic Pathways**





- Scientific research and clinical experience illustrating that people with autism spectrum and other neurodevelopmental disorders function better when certain nutrients are supplemented at high doses.
- The data supporting nutritional support in autism is strongest for the following nutrients:
  - Carnitine
  - Coenzyme Q10
  - Magnesium
  - Pyridoxine (vitamin B6)
  - Cobalamin (vitamin B12)
  - Vitamin D3





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  - Vitamin D3

All of these nutrients are important in energy metabolism and are standard components of the "mitochondrial (mito) cocktail".





## Mitochondrial Metabolism in Autism

- 1. The scientific research that reveals about one-half of individuals on the autism spectrum have mitochondrial deficiencies (see Frye & Rossignol).
- 2. The "mito-cocktail" refers to combined nutritional support for mitochondrial dysfunction.
- 3. The mito-cocktail is ill-defined, but generally consists of about 10-30 different nutrients.
- 4. SpectrumNeeds<sup>™</sup> includes the following components of the mito-cocktail:
  - Acetyl L-carnitine
  - Alpha ketoglutarate
  - Alpha lipoic acid
  - Carnitine
  - Coenzyme Q10
  - Creatine
  - Magnesium
  - Zinc



- Vitamins
  - B1 (thiamine)
  - B2 (riboflavin)
  - B3 (niacinamide)
  - B5 (pantothenate)
  - B6 (pyridoxine, pyridoxal-5-phosphate)
  - B7 (biotin)
  - B12 (methylcobalamin)
  - C
  - D3

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## UNITED MITOCHONDRIAL DISEASE FOUNDATION® HOPE. ENERGY. LIFE.

#### Brain

- Developmental delays
- Dementia
- Neuro-psychiatric disturbances
- Migraines
- Autistic Features
- Mental retardation
- Seizures
- Atypical cerebral palsy
- Strokes

#### Nerves

- Weakness (may be intermittent)
- Absent reflexes
- Fainting
- Neuropathic pain
- Dysautonomia temperature instability

#### Muscles

- Weakness
- Cramping

- Gastrointestinal problems
- Dysmotility
- Irritable bowel syndrome
- Hypotonia
- Muscle pain
- Gastroesophogeal reflux
- Diarrhea or constipation
- Pseudo-obstruction

#### Kidneys

Renal tubular acidosis or wasting

#### Heart

- Cardiac conduction defects (heart blocks)
- Cardiomyopathy

#### Liver

- Hypoglycemia (low blood sugar)
- Liver failure

# Mitochondrial Medicine The Spectrum of Mito

#### Ears & Eyes

- Visual loss and blindness
- Ptosis
- Ophthalmoplegia
- Optic atrophy
- Hearing loss and deafness
- Acquired strabismus
- Retinitis pigmentosa

#### Pancreas & other glands

- Diabetes and exocrine pancreatic failure (inability to make digestive enzymes)
- Parathyroid failure (low calcium)

#### Systemic

- Failure to gain weight
- Fatigue
- Unexplained vomiting
- Short stature
- Respiratory problems



# Case Study: Autism & Chronic Pain: Big Zach

- Autism early infancy
  - Lost language skills acquired at 18 months.
  - Diagnosed with autism at age 2 years.
- Cyclic vomiting syndrome age 6 years
  - Episodes of nausea, vomiting and lethargy lasting from a few days to a week or more.
- Bowel dysmotility
  - Hospitalized many times for "clean-outs".
  - Multiple procedures to place tubes in different bowel segments.
- Complex regional pain syndrome age 12 yrs
  - Episodes in which right foot becomes cold, purple, tender, allodynia, unable to bear weight; wheelchair bound for months.
- Other chronic intermittent symptoms
  - Headache, muscle pain, photophobia, ptosis, tics, hours-long episodes of hiccups.
- Severe exercise intolerance







# Case Study: Autism & Chronic Pain: Big Zach

- Autism
- Complex regional pain syndrome
- Cyclic vomiting syndrome
- Bowel dysmotility
- Severe exercise intolerance
- Biochemical laboratory testing strongly suggested a mitochondrial disorder.
- Placed on mitochondrial cocktail:
  - Alpha lipoic acid
  - Coenzyme Q10
  - L-carnitine
  - Riboflavin
  - Vitamin B complex
  - Vitamin C
  - Vitamin D3
- Cocktail was associated with substantial improvements:
  - Pain-free and weaned off opiates
  - Cyclic vomiting episodes stopped







## Case Study: Singleton Autism: Carter



- Presented at age 1 year following the MMR vaccination in which he stopped developing speech for the next year.
- He was later diagnosed with an autistic spectrum disorder.
- Biochemical laboratory testing had suggested the possibility of a mitochondrial disorder.
- Placed on basic mitochondrial cocktail:
  - Coenzyme Q10
  - Creatine
  - Folinic acid
  - L-carnitine
  - Riboflavin
- Cocktail "opened his brain": talking more, more socially and emotionally engaged, can reason with him better and less temper tantrums.





Nutritional Support in Autism Carnitine and Acetylcarnitine

- What It Does: 1. Ferries long-chain fatty acids into mitochondria. 2. Detoxifying by ferrying incompletely oxidized metabolic intermediates out of the mitochondria
- Deficiency: Fatigue, weakness, cardiomyopathy
- In ASD: Several published studies have shown positive effects of carnitine supplementation in individuals on the autistic spectrum, including a reduction in autistic behaviors.
- Forms: Acetylcarnitine (ALCAR) is a form of carnitine that can more easily cross membranes, and thus is used for a variety of brain disorders.
- Side Effects: Rare at moderate dosing; can include a fishy odor that can be treated by riboflavin or antibiotics.
- Caveats: Critically important in patients with metabolic disorders. Laboratory testing can help optimize supplementation; levels of free carnitine in the blood over 30 to 40 mcmole/L are associated with improved outcomes.





- What It Does: 1. Electron carrier in the respiratory chain. 2. Antioxidant, protecting the body from damage caused by ROS.
- Deficiency: Mitochondrial disease, including fatigue, weakness, cardiomyopathy
- In ASD: One study in children with ASD reported that significant improvements were noted, including in communication and social skills as well as sleeping. However, the role of coQ10 in the treatment of autism is mostly driven by its antioxidant properties for the treatment of mitochondrial dysfunction.
- Forms: Ubiquinol has better bioavailability than the usual form of ubiquinone, but is not stable in powder form.
- Side Effects: Rare at moderate dosing, except for insomnia if given at bedtime.
- Caveats: Critically important in patients with mitochondrial disorders.
  Laboratory testing can help optimize supplementation; levels over 3-4 mg/L are associated with improved outcomes. May require additional supplementation.





## Nutritional Support in Autism Magnesium

- What It Does: 1. Mineral required for the function of over 300 enzymatic reactions, including in energy metabolism where it plays a pivotal role. 2. Agonist for GABA receptors and an antagonist for NMDA glutamate receptors.
- Deficiency: Common, particularly in vulnerable populations, including people with GI disease; loss of appetite, nausea, vomiting, fatigue, weakness, anxiety, memory problems, numbness and tingling, tics, cramps, insomnia, seizures, personality changes, and abnormal heart rhythms.
- In ASD: Evaluated in a few studies, some of which have shown benefit, especially when coupled with pyridoxine.
- Forms: Supplements are available over-the-counter in a variety of forms, some are more bioavailable than others. Mg glycinate and Mg citrate are often recommended.
- Side Effects: Rare at moderate dosing except for loose stools with Mg citrate.
- Caveats: Also helpful for constipation, migraine/chronic pain, fatigue, restless leg, signs of insulin resistance, and indications of reduced inhibitory–excitatory balance (anxiety, hyperactivity, impulsivity, OCD, etc.).





## Nutritional Support in Autism Pyridoxine and P5P (vitamin B6)

- What It Does: 1. Vitamin required for the function of over 100 enzymatic reactions, including in metabolism where it plays a pivotal role. 2. Involved in critical pathways such as neurotransmission, myelination, and gene expression.
- Deficiency: Fatigue, weakness, depression, peripheral neuropathy, seizures
- In ASD: Evaluated in a few studies, some of which have shown benefit, especially when coupled with magnesium.
- Forms: Activated form is pyridoxal-5-phosphate (P5P, PLP)
- Side Effects: Rare at moderate dosing.
- Caveats: One study suggests that pyridoxine activation may be defective in ASD, arguing for P5P supplementation.





- What It Does: 1. Cofactor for enzymes in metabolism. 2. Role in myelination.
- Deficiency: Common, including fatigue, weakness, problems walking, psychosis, and behavioral changes, which may be irreversible.
- In ASD: Several studies in children with ASD using methylcobalamin injection have revealed improved glutathione metabolism or methylation and/or significant clinical improvements, especially in adaptive behaviors.
- Forms: Activated form is methylcobalamin.
- Side Effects: Rare at moderate dosing.
- Caveats: Oral dosing has not been well studied in ASD, but makes sense to try prior to progressing to injections.





## Nutritional Support in Autism Vitamin D3

- What It Does: In addition to its role in bone, vitamin D has several other effects, including on brain development, neurotrophic and neuroprotective actions, neurotransmission, synaptic plasticity, immune function, and regulation of gene expression.
- Deficiency: Common even among individuals with light skin tones.
- In ASD: Several studies have documented that vitamin D deficiency is common among children with ASD. In one study, 87% had 25-hydroxyvitamin D levels below 30 ng/ml. A few clinical trials have demonstrated clinical improvement in children with ASD following supplementation, including in 81% with better outcomes with treatment blood levels over 40 ng/ml.
- Forms: 25-hydroxyvitamin D3 is the active form, which is easily made from vitamin D3.
- Side Effects: Rare at moderate dosing.
- Caveats: Monitoring blood levels of 250H-vitamin D is important in monitoring • therapy. Aim for a level > 30, possibly > 40. 17



# Case Study: Autism as Part of a Complicated Condition: Kelly

- Presented to my clinic as a teenager
- Autistic spectrum disorder
- Main issue was continuous migraine headache
- Chronic fatigue syndrome severe, disabling.
- Bowel dysmotility/IBS
- Dysautonomia, including tachycardia and POTS
- Depression and anxiety severe, disabling







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- Two predicted mutations were identified in the gene that encodes an enzyme that converts glutamine to glutamate
- This gene/protein regulates cellular energy metabolism by increasing production of glutamate and alpha-ketoglutarate.
- Started on alpha-ketoglutarate supplementation.
- "The supplements seem to have made a remarkable difference! Her symptoms are much better controlled and mostly manageable & she has been able to resume some of her daily activities & a small amount of local travel. This has lifted her spirits greatly. It hasn't "cured" it all but is is quite a miracle all the same." 19





Children on the autism spectrum often have diets that are deficient in many nutrients shown by low levels in blood or hair.

- Choline
- Chromium
- Magnesium
- Manganese
- Molybdenum
- Selenium
- Zinc

- Vitamins
  - B1 (thiamine)
  - B5 (pantothenate)
  - B6 (pyridoxine, pyridoxal-5phosphate)
  - B7 (biotin)
  - B9 (folate)
  - B12 (methylcobalamin)
  - C
  - D3
  - E





Children on the autism spectrum often have diets that are deficient in many nutrients shown by low levels in blood or hair.

- Choline
- Chromium
- Magnesium
- Manganese
- Molybdenum
- Selenium
- Zinc

However, nutritional therapy generally works by providing extremely high levels of selected nutrients in order to push specific pathways in the desired directions.

- Vitamins
  - B1 (thiamine)
  - B5 (pantothenate)
  - B6 (pyridoxine, pyridoxal-5phosphate)
  - B7 (biotin)
  - B9 (folate)
  - B12 (methylcobalamin)
  - C
  - D3
  - E





- Standard multivitamin supplement may not always be absorbed and utilized.
  - Activated vitamin B6 as pyridoxal 5-phosphate (P5P)
  - Activated vitamin B9 (folate) as
    - 6S-5-L-methyltetrahydrofolate glucosamine
    - calcium folinate
  - Activated vitamin B12 as methylcobalamin



Effect of a vitamin/mineral supplement on children and adults with autism. Adams et al, 2011, PMID 22151477.

- Randomized, double-blind, placebo-controlled
- 141 children and adults with autism
- 3-months of placebo or a vitamin/mineral cocktail consisting of 31 ingredients
- Improvements in the PGI-R (Average Change, p = 0.008), and on the subscores for Hyperactivity (p = 0.003), Tantrumming (p = 0.009), Overall (p = 0.02), and Receptive Language (p = 0.03).
- Improvements in methylation, glutathione, oxidative stress, sulfation, ATP, NADH, and NADPH.



## The Science Behind Supplements The Kaplan Studies

Tools

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Journal of Child and Adolescent Psychopharmacology, Vol. 12, No. 3 | Original Research

## Treatment of Mood Lability and Explosive Rage with Minerals and Vitamins: Two Case Studies in Children

Bonnie J. Kaplan, Susan G. Crawford, Beryl Gardner, Geraldine Farrelly

Published Online: 5 Jul 2004 | https://doi.org/10.1089/104454602760386897

#### View Article

### Abstract

A micronutrient supplement containing a broad range of dietary minerals and vitamins is being examined for the treatment of mood lability in both adults and children (Kaplan et al. 2001; Popper 2001). During pilot work, two medication-free boys with mood lability and explosive rage were studied in an open-label treatment followed by reversal and retreatment. One child was an 8-year-old with atypical obsessive-compulsive disorder, and the other was a 12-year-old with pervasive developmental delay. Both boys were monitored using the mood and temper items from the Conners Parent Rating Scale, as well as the Child Behavior Checklist. In addition, the boy with atypical obsessive-compulsive disorder was monitored with the child version of the Yale-Brown Obsessive Compulsive Scale. Both boys benefited from the micronutrient supplement when examined in ABAB designs: mood, angry outbursts, and obsessional symptoms improved when initially treated, returned when not taking the supplement, and remitted when the micronutrient supplement was reintroduced. Both boys have been followed and are stable on the nutritional supplement for over 2 years. These cases suggest that mood lability and explosive rage can, in some cases, be managed with a mixture of biologically active minerals and vitamins, without using lithium or other traditional psychopharmacologic agents.



## The Science Behind Supplements The Kaplan Studies

Table 1 Comparison of EMPowerplus ingredients with Tolerable Upper Intake Levels (ULs)

	Amount in a typical therapeutic dose, 15 capsules daily	UL
Vitamin A	5,760 IU	10,000 IU
Vitamin C	600 mg	2,000 mg
Vitamin D	1,440 IU	2,000 IU
Vitamin E	360 IU	1,500 IU
Vitamin B1	18 mg	none set
Vitamin B2	13.5 mg	none set
*Vitamin B3	90 mg	35 mg
Vitamin B5	21.6 mg	none set
Vitamin B6	36 mg	100 mg
<sup>b</sup> Folate	1,440 mcg	1,000 mcg
Vitamin B-12	900 mcg	none set
Vitamin H	1,080 mcg	none set
Calcium	1,320 mg	2,500 mg
Phosphorous	840 mg	4,000 mg
<sup>c</sup> Magnesium	600 mg	350 mg
Potassium	240 mg	none set
lodine	204 mcg	1,100 mcg
dZinc	48 mg	40 mg
Selenium	204 mcg	400 mcg
Copper	7.2 mg	10 mg
Manganese	9.6 mg	11 mg
Chromium	624 mcg	none set
Molybdenum	144 mcg	2,000 mcg
Iron	13.74 mg	45 mg

- This formula is very similar to the general nutrition aspects of SpectrumNeeds<sup>™</sup>.
- What is absent in this formula is the high-dose mitochondrial cocktail.

Plus a proprietary formula of dl-phenylalanine, glutamine, citrus bioflavonoids, grape seed extract, choline bitartrate, inositol, ginkgo biloba, methionine, germanium sesquioxide, boron, vanadium, nickel.



## The Science Behind Supplements The Kaplan Studies

Simpson et al. BMC Psychiatry 2011, 11:62 http://www.biomedcentral.com/1471-244X/11/62

**RESEARCH ARTICLE** 



Open Access

### Systematic review of safety and tolerability of a complex micronutrient formula used in mental health

J Steven A Simpson<sup>1</sup>, Susan G Crawford<sup>2</sup>, Estelle T Goldstein<sup>3</sup>, Catherine Field<sup>4</sup>, Ellen Burgess<sup>5</sup> and Bonnie J Kaplan<sup>6,7\*</sup>

#### Abstract

Background: Theoretically, consumption of complex, multinutrient formulations of vitamins and minerals should be safe, as most preparations contain primarily the nutrients that have been in the human diet for millennia, and at safe levels as defined by the Dietary Reference Intakes. However, the safety profile of commercial formulae may differ from foods because of the amounts and combinations of nutrients they contain. As these complex formulae are being studied and used clinically with increasing frequency, there is a need for direct evaluation of safety and tolerability.

Methods: All known safety and tolerability data collected on one complex nutrient formula was compiled and evaluated.

**Results:** Data were assembled from all the known published and unpublished studies for the complex formula with the largest amount of published research in mental health. Biological safety data from 144 children and adults were available from six sources: there were no occurrences of clinically meaningful negative outcomes/effects or abnormal blood tests that could be attributed to toxicity. Adverse event (AE) information from 157 children and adults was available from six studies employing the current version of this formula, and only minor, transitory reports of headache and nausea emerged. Only one of the studies permitted a direct comparison between micronutrient treatment and medication: none of the 88 pediatric and adult participants had any clinically meaningful abnormal laboratory values, but tolerability data in the group treated with micronutrients revealed significantly fewer AEs and less weight gain.

**Conclusions:** This compilation of safety and tolerability data is reassuring with respect to the broad spectrum approach that employs complex nutrient formulae as a primary treatment.



## The Science Behind Supplements Additional Studies

- Micronutrients Versus Standard Medication Management in Autism: A Naturalistic Case–Control Study; PMID 20415604.
- Systematic review of safety and tolerability of a complex micronutrient formula used in mental health; PMID 21501484.
- Treatment of Mood Lability and Explosive Rage with Minerals and Vitamins: Two Case Studies in Children; PMID 12427294.
- Nutritional and metabolic status of children with autism vs. neurotypical children, and the association with autism severity; PMID 21651783.
- The effect of dietary supplements on clinical aspects of autism spectrum disorder: A systematic review of the literature; PMID 28438367.
- How nutritional status, diet and dietary supplements can affect autism. A review; PMID 23789306.
- Dietary Supplement for Core Symptoms of Autism Spectrum Disorder: Where Are We Now and Where Should We Go?; PMID 28878697.
- Identification and Treatment of Pathophysiological Comorbidities of Autism Spectrum Disorder to Achieve Optimal Outcomes; PMID 27330338.
- A comprehensive systematic review and meta-analysis of pharmacological and dietary supplement interventions in paediatric autism: moderators of treatment response and recommendations for future research; PMID 28091344.
- Metabolic approaches to the treatment of autism spectrum disorders; PMID 11098885.
- Novel and emerging treatments for autism spectrum disorders: a systematic review; PMID 19917212.<sup>27</sup>



## Nutritional Support in Autism **SpectrumNeeds**<sup>™</sup>



Medical Geneticist and

Pediatrician



Child Neurologist and Pediatrician



Michael W. Elice, M.D. Pediatrician



Richard E. Frve, M.D. Pediatrician



Daniel A. Rossignol, M.D.



Mark Mintz, M.D. Pediatrician



Jared M. Skowron, M.D. Dedicated to disorders

Dr. Audrey E. Griesbach M.D. FAAP. Developmental and Behavioral Pediatrician

### **Designed by Prominent Physicians and Scientists** To Unlock the Body's Full Potential

SpectrumNeeds™ is a nutritional supplement containing vitamins, minerals, and activated cofactors used to optimize the nutritional status of children and adults with autism spectrum and other neurodevelopmental disorders (including ADD/ADHD), used to stimulate specific biological pathways in order to promote health.

"I am very excited about having a nutritional I can trust that covers so many needs for many of my kids!" -Dr. Audrey Griesbach

- Increases Nutritional Support (Adams +)
- Corrects Dietary Deficiencies (incl. rare trace nutrients)
- Promotes Mitochondrial Metabolism (high dose)
- Activated Form (B6, B9-folate, B12)
- Expert Formulation (see creators above)
- High Quality (USA, CGMP)





- SpectrumNeeds<sup>™</sup> is based on the Adams formula.
- However, there are some substantial differences between SpectrumNeeds<sup>™</sup> and the product studied by Adams et al. SpectrumNeeds<sup>™</sup>:
  - Includes alpha lipoic acid, a powerful antioxidant.
  - Includes creatine to promote neuronal energy metabolism.
  - Includes carnitine and acetylcarnitine to assist in removing harmful organic acids from mitochondria.
  - Includes activated vitamin B6 (P5P), which has emerging associations with brain disorders.
  - Includes the Krebs cycle intermediates alpha ketoglutarate, citrate, and malate, to promote energy metabolism.
  - Includes arginine to assist with small vessel circulation in the brain and elsewhere.
  - The dose of vitamin B5 (pantothenate), which is the source of coenzyme A required in multiple enzymes, is 20 times higher.
  - The dose of coenzyme Q10, a crucial nutrient in mitochondrial energy metabolism and antioxidant, is 5 times higher.
  - The dose of vitamin D, which is associated with ASD in many studies, is doubled.
  - The dose of magnesium, which is important for energy metabolism and selected neurotransmission, is doubled.
  - Has higher amounts of both activated folate and folinate, the latter of which provides folate directly to brain.



## Nutritional Support in Autism SpectrumNeeds<sup>™</sup> – Back of Label

### Supplement Facts

Serving Size: 2 Heaping Scoops (4.4 g) Servings Per Container: 60

a	knount Per Serving	% Daily Value Children under 4 years of age	% Daily Value Children 4 or more years of age
Vitamin C (as ascorbic acid)	300 mg	2,000%	333%
Vitamin D (as cholecalciferol)	7.5 mcg (300 IU)	50%	38%
Vitamin E (as d-alpha-tocopheryl acetate and mixed tocopherols)	25 mg	417%	167%
Thiamin (as thiamin HCI)	12.5 mg	2,500%	1,042%
Riboflavin	12.5 mg	2,500%	962%
Niacin (as niacinamide)	12.5 mg	208%	78%
Vitamin B6 (50% as pyridoxine HCI and 50% as pyridoxal-5-phosphate)	10 mg	2,000%	588%
Folate (as 6S-5-Methyltetrahydrofolic acid glucosamine salt (Quatrefolic®) and calcium folinate)	1,667 mcg DFE	1,111%	417%
Vitamin B12 (as methylcobalamin)	250 mcg	27,778%	10,417%
Biotin	500 mcg	6,250%	1,667%
Pantothenic acid (as D-calcium pantothenate)	150 mg	7,500%	3,000%
Calcium	30 mg	4%	2%
lodine (as potassium iodide)	50 mcg	56%	33%
Magnesium (as magnesium citrate and magnesium malate	) 100 mg	125%	24%
Zinc (as zinc gluconate)	6 mg	200%	55%
Selenium (as selenomethionine)	25 mcg	125%	45%
Manganese (as manganese amino acid chelate)	0.5 mg	42%	22%
Chromium (as chromium picolinate)	25 mcg	227%	71%
Molybdenum (as sodium molybdate)	50 mcg	294%	111%
Potassium (as potassium citrate)	25 mg	<1%	<1%
Creatine monohydrate	625 mg	t	t
L-Arginine	500 mg	t	t
Carnitine Blend (acetyl L-carnitine HCI and L-carnitine)	250 mg	t	+
Alpha ketoglutaric acid	150 mg	t	Ť
Coenzyme Q10	125 mg	t	+
Choline bitartrate	75 mg	Ť	t
Inositol	50 mg	Ť	t
Alpha lipoic acid	50 mg	t	+
D-Beta, D-Gamma, D-Delta tocopherols	2.2 mg	t	+

DIRECTIONS: Mix with water, juice, or other beverage according to dosage chart below. Stir to mix well. Drink one serving twice a day, preferably with food.

Body Weight	Spectrum Needs Amount Per Serving	Suggested Beverage Volume
22-33 lbs (10-15 kg)	1 Heaping Scoop (2.2 grams)	2 fl. oz.
33-44 lbs (15-20 kg)	1.5 Heaping Scoops (3.3 grams)	3 fl. oz.
44-88 lbs (20-40 kg)	2 Heaping Scoops (4.4 grams)	4 fl. oz.
88-132 lbs (40-60 kg)	2.5 Heaping Scoops (5.5 grams)	5 fl. oz.
132+ lbs (60+ kg)	3 Heaping Scoops (6.6 grams)	6 fl. oz.

Free of all common allergens, including gluten, dairy/casein, eggs, soy, fish/shellfish, peanuts, and nuts.



Warnings: As with any dietary supplement, If you are pregnant, nursing, or taking medication, consult your physician before use.

- · Keep out of reach of children. · Protect from heat, light and moisture.
- Store in a cool, dry place.
- · Do not purchase if inner seal is broken.

Other ingredients: Citric acid, natural flavors, organic glucosylated steviol glycosides, organic rebaudioside A, silica and monk fruit extract.





Case Study: Singleton Autism: Carter – After Genetic Testing



- Presented at age 1 year following the MMR vaccination in which he stopped developing speech for the next year.
- He was later diagnosed with an autistic spectrum disorder.
- Biochemical laboratory testing had suggested the possibility of a mitochondrial disorder.
- Placed on basic mitochondrial cocktail:
  - Coenzyme Q10
  - Creatine
  - Folinic acid
  - L-carnitine
  - Riboflavin
- Cocktail "opened his brain": talking more, more socially and emotionally engaged, can reason with him better and less temper tantrums.
- Years later, genetic testing revealed a disease-associated variant in the *TRAP1* gene at p.lle253Val.





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- Years later, genetic testing revealed a disease-associated variant in the *TRAP1* gene at p.lle253Val.
- Following informed consent, a drug determined by in silico design was tried in Carter. The anecdotal results were clear and dose-dependent, in that on the drug Carter was:
  - more talkative, expresses himself better
  - more clever
  - more focused\*
  - less aggressive\*
  - less sensory integration issues\*
  - gets along better with his older brother
  - more tolerate of previously-difficult situations.



## Case Study: Autism & Chronic Pain: Big Zach – After Genetic Testing

- Autism
- Complex regional pain syndrome
- Cyclic vomiting syndrome
- Bowel dysmotility
- Severe exercise intolerance



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- Placed on mitochondrial cocktail.
- Cocktail was associated with substantial improvements.
- Years later, genetic testing revealed a likely disease-associated variant in the *CHAT* gene that encodes for the enzyme that catalyzes the synthesis of acetylcholine in cholinergic neurons.





## Case Study: Autism & Chronic Pain: Big Zach – After Genetic Testing

- Autism
- Complex regional pain syndrome
- Cyclic vomiting syndrome
- Bowel dysmotility
- Severe exercise intolerance
- Biochemical laboratory testing strongly suggested a mitochondrial disorder.
- Placed on mitochondrial cocktail.
- Cocktail was associated with substantial improvements.
- Years later, genetic testing revealed a likely disease-associated variant in the *CHAT* gene that encodes for the enzyme that catalyzes the synthesis of acetylcholine in cholinergic neurons.
- Following informed consent, an anticholinesterase drug was tried in Zach. The anecdotal results were clear and dose-dependent, in that on the drug Zach was:
  - Went from echolalia to being far more talkative, expressing himself better, even speaking in complete sentences.





- Omega-3 long chain polyunsaturated fatty acids ("Omega 3s"):
  - The only nutrient that experts often recommend in neurodevelopmental disorders that is absent from SpectrumNeeds<sup>™</sup>.
  - These fatty acids are not well absorbable from a powder.
  - However, omega 3s have been demonstrated to be low in patients with autistic spectrum disorders and supplementation with omega 3s has been demonstrated to have some efficacy.
- Coenzyme Q10 (coQ10):
  - SpectrumNeeds<sup>™</sup> has a high dose of this nutrient, but may not be sufficient in every individual to achieve desirable blood levels and nutritional goals.
  - Discuss with your health care provider regarding blood testing for a coQ10 level and/or additional supplementation with ubiquinol, a form of coQ10 that is poorly absorbable from powder, and thus not included in SpectrumNeeds™.
- Others additional information is our website:
  - B12, folinate, Mg, Zn: High dosing may not be high enough in some
  - Cu/Fe/Ca/vitamin A: Excluded for potential toxicity in some patients
  - Some providers will want additional supplementation in some patients.



## Adapting SpectrumNeeds<sup>™</sup> For Mitochondrial Disease

- Coenzyme Q10 (coQ10):
  - SpectrumNeeds<sup>™</sup> has a high dose of this nutrient, but may not be sufficient in every individual to achieve desirable blood levels and nutritional goals.
  - Discuss with your health care provider regarding blood testing for a coQ10 level and/or additional supplementation with ubiquinol, a form of coQ10 that is poorly absorbable from powder, and thus not included in SpectrumNeeds™.
- Others nutrients that may need higher dosing:
  - Alpha lipoic acid strong antioxidant, but limited by nausea
  - Magnesium higher dosing may be useful in migraine, constipation
  - Riboflavin higher dosing may be useful in migraine
  - Vitamin D higher dosing may be useful depending on blood levels
  - Some providers will want additional supplementation in some patients.



## Adapting SpectrumNeeds<sup>™</sup> For Mitochondrial Disease

- Coenzyme Q10 (coQ10):
  - SpectrumNeeds<sup>™</sup> has a high dose of this nutrient, but may not be sufficient in every individual to achieve desirable blood levels and nutritional goals.
  - Discuss with your health care provider regarding blood testing for a coQ10 level and/or additional supplementation with ubiquinol, a form of coQ10 that is poorly absorbable from powder, and thus not included in SpectrumNeeds™.
- Others nutrients that may need higher dosing:
  - Alpha lipoic acid strong antioxidant, but limited by nausea [add 100 mg BID]
  - Magnesium higher dosing may be useful in migraine, constipation [add 250 mg daily]
  - Riboflavin higher dosing may be useful in migraine [add one B100 tablet a day]
  - Vitamin D higher dosing may be useful depending on blood levels
  - Some providers will want additional supplementation in some patients.

Cheat sheet: Add above in an adult to convert from an autism cocktail to a mito cocktail.Add half of the above in an elementary school-aged child.As always, consult your physician before making any supplement changes.37



## Adapting SpectrumNeeds<sup>™</sup> For Mitochondrial Disease

	Current Receiving In Cocktail	SpectrumNeeds™ Provides (44-88 lbs)	Example Changes to Supplement
Alpha lipoic acid	100 mg BID	50 mg BID	Give 100 mg daily
Coenzyme Q10	100 mg BID	125 mg BID	Stop supplement or no changes
Magnesium	250 mg daily	100 mg BID	Probably can stop taking supplement
Riboflavin	100 mg daily	12.5 mg BID	No changes
Ribose	2.5 grams BID	None	No changes
Vitamin C	500 mg daily	300 mg BID	Ston sunnlement
Vitamin D			Depends 28
Riboflavin Ribose Vitamin C Vitamin D	100 mg daily 2.5 grams BID 500 mg daily 1,000 IU daily	12.5 mg BID None 300 mg BID 300 IU BID	No changes No changes Stop supplement Depends 38



## What Does SpectrumNeeds<sup>™</sup> Add for "Mito" Patients?

## **Supplement Facts**

Serving Size: 2 Heaping Scoops (4.4 g) Servings Per Container: 60

	Amount Per Serving	% Daily Value Children under 4 years of age	% Daily Value Children 4 or more years of age
Vitamin C (as ascorbic acid)	300 mg	2,000%	333%
Vitamin D (as cholecalciferol)	7.5 mcg (300 IU)	50%	38%
Vitamin E (as d-alpha-tocopheryl acetate and mixed tocopherols)	25 mg	417%	167%
Thiamin (as thiamin HCI)	12.5 mg	2,500%	1,042%
Riboflavin	12.5 mg	2,500%	962%
Niacin (as niacinamide)	12.5 mg	208%	78%
Vitamin B6 (50% as pyridoxine HCI and 50% as pyridoxal-5-phosphate)	10 mg	2,000%	588%
Folate (as 6S-5-Methyltebrahydrofolic acid glucosamine salt (Quatrefolic®) and calcium folinate)	1,667 mcg DFE	1,111%	417%
Vitamin B12 (as methylcobalamin)	250 mcg	27,778%	10,417%
Biotin	500 mcg	6,250%	1,667%
Pantothenic acid (as D-calcium pantothenate)	150 mg	7,500%	3,000%
Calcium	30 mg	4%	2%
lodine (as potassium iodide)	50 mcg	56%	339
Magnesium (as magnesium citrate and magnesium malat	e) 100 mg	125%	249
Zinc (as zinc gluconate)	6 mg	200%	55%
Selenium (as selenomethionine)	25 mcg	125%	45%
Manganese (as manganese amino acid chelate)	0.5 mg	42%	223
Chromium (as chromium picolinate)	25 mcg	227%	719
Molybdenum (as sodium molybdate)	50 mcg	294%	1119
Potassium (as potassium citrate)	25 mg	<1%	<1%
Creatine monohydrate	625 mg	t	
L-Arainine	500 mg	Ť	33
Carnitine Blend (acetyl L-carnitine HCI and L-carnitine)	250 mg	t	
Alpha ketoqlutaric acid	150 mg	t	
Coenzyme Q10	125 mg	†	15
Choline bitartrate	75 mg	t	
inositol	50 mg	t	8
Alpha lipoic acid	50 mg	Ť	
	2.2 ma	+	

• Neuroprotection:

- Activated B6
- Activated folate
- Activated B12
- Magnesium
- Zinc
- Additional mito-cocktail:
  - Alpha ketoglutarate
  - Creatine
  - Vitamin B5
  - Selenium
- Other
  - Comprehensive nutrition
  - Arginine
  - Chromium

Other ingredients: Citric acid, natural flavors, organic glucosylated steviol glycosides, organic rebaudioside A, silica and monk fruit extract.



## Nutritional Support SpectrumNeeds™

- Promotes mitochondrial energy metabolism.
- Generates essential cofactors, such as coenzyme A.
- Provides strong antioxidant support for free radical removal.
- Removes harmful metabolites, including certain organic acids.
- Enhances methylation needs, and thereby assist in gene regulation.
- Facilitates selected neurotransmission, including GABA receptors.
- Protects the nervous system, including by reducing NMDA glutamate receptor activity.
- Assists in the regulation of insulin control.
- Improves small vessel circulation in the brain. The above claims have not been reviewed by the FDA.

33 Active Ingredients



Buy/learn about SpectrumNeeds™: <u>https://neuroneeds.com</u>

Refer a patient for telemedicine: <a href="https://cnnh.org">https://cnnh.org</a>