



Georgia Department of Public Health

Special Formula and Medical Documentation

Part 3: Qualifying Medical Conditions and Diagnoses
Presented by: Denice Vance, MS, RD, LD, CLC
Date: February 6, 2017



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Objectives

Following this presentation attendees will be able to:

- Determine acceptable qualifying medical conditions for the issuance of special formula
- Understand the relationship between the medical diagnoses and intended use
- Recognize which conditions require additional documentation
- Appropriately use state created and available manufacturer resources as a reference when issuing special formula

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Medical Diagnoses

- A specific, qualifying medical condition is necessary prior to the issuance of any formula or nutritional that requires medical documentation
 - Consistent with the manufacturer's **labeled and intended use** of the formula or nutritional prescribed
 - OR
 - Consistent the **nutrient composition and nutritional features** indicated in the management of the specified condition

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Medical Diagnoses

- Continued...
 - Consistent with the participant's anthropometric data (e.g., length/height, weight, BMI) and WIC nutritional assessment for authorization of issuance
 - A "suspected" diagnosis is allowable as long as it still meets the other diagnostic criteria (e.g., "suspected milk protein allergy")

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Medical Diagnoses Requiring Additional Documentation

- Non-specific, general medical diagnoses are not sufficient as Georgia WIC medical documentation
 - Milk/Formula intolerance
 - Multiple food allergies (specify)
 - Feeding difficulties/feeding problems

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Medical Diagnoses Requiring Additional Documentation

- Clinical signs and symptoms are not permitted for use as the sole diagnosis for WIC medical documentation
 - Colic/fussiness
 - Spitting up
 - Digestive disturbances
 - o Constipation
 - o Gas

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Medical Diagnoses Requiring Additional Documentation

- Diagnoses solely for the purpose of enhancing nutrient intake or managing body weight without an underlying qualifying condition
 - Picky eater/poor appetite
 - Inadequate/poor intake
 - Underweight
 - Inadequate/poor weight gain

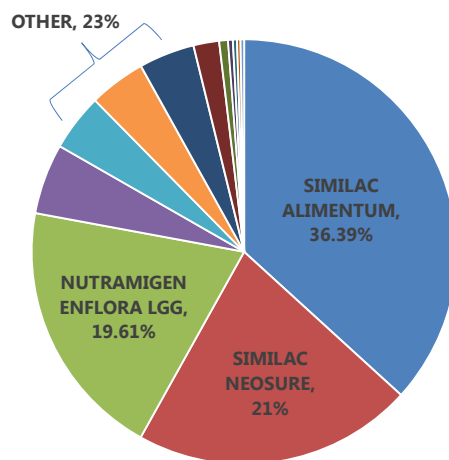
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Infant Special Formula Food Package Issuance by Participant

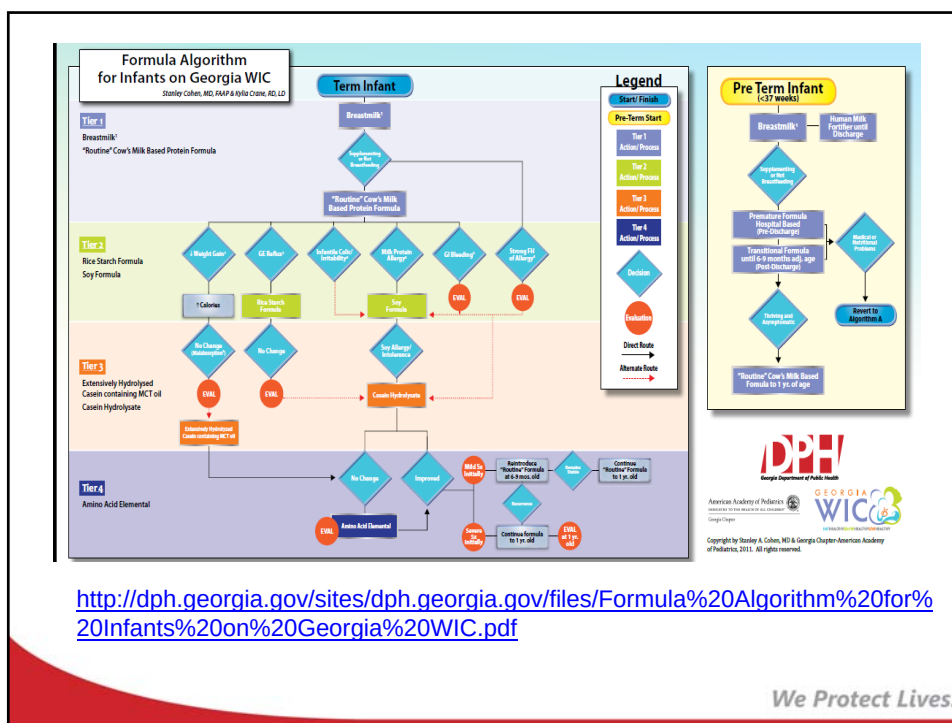
(October 2016 Closeout Data)

Special Formula Issuance

- Non-Contract Formula Issuance
 - Enfamil AR (Powder): 261
- Exempt Formula Issuance
 - Similac Alimentum (Powder): 3,114
 - Similac Neosure (Powder): 1,805
 - Nutramigen (Powder): 1,678
 - All other special formula combined: 1,961



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What About Soy Formula?

- Although soy formula may be tolerated in some instance of milk protein allergy/intolerance, a soy formula trial **is not required**
- If soy is recommended, but refused by the provider:
 - Document the refusal on the MDF
 - Proceed with issuance of hydrolysate formula

Diagnosis(es) and Indicated Use

- Cow's milk protein allergy/intact protein sensitivity
- GERD with failure of Enfamil AR
 - Protein Hydrolysate Infant Formulas
 - Similac Alimentum
 - Nutramigen
 - Gerber Extensive HA

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Sensitivity vs. Allergy

- Cow's milk protein sensitivity can be used instead of allergy as a diagnosis
- Some doctors will only use the term allergy when they have IGG testing to support a formal diagnosis

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What is the intended use for...

Similac Neosure?

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Prematurity/Low Birth Weight

- 22 kcal formulas are appropriate to use through 12 months or corrected age equivalent
 - Similac Neosure
 - Enfamil EnfaCare

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Prematurity/Low Birth Weight

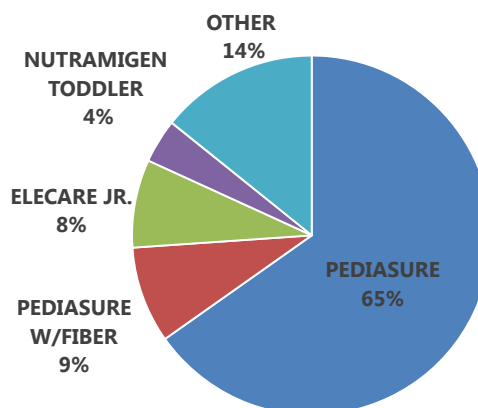
- 24 and 30 calorie premature formulas (i.e. Similac Special Care 24) are rarely issued post discharge as they are intended to be used under direct medical supervision
- Recommend to discontinue use per manufacturer's instructions
 - Risk for excessive intake of fat soluble vitamins
- Follow up with provider regarding their transition plan. Continued issuance past 6 months will require additional provider documentation

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Child Formula Food Package Issuance by Participant

(October 2016 Closeout Data)

- Pediasure: 1,637
- Pediasure w/Fiber: 218
- Elecare Junior: 178
- Nutramigen Toddler: 99
- Other: 357



* Does not include state ordered issuance*

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What is the indicated use for...

Pediasure?

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Failure to Thrive/Feeding Difficulties

- Failure to thrive (consistent with WIC growth assessment)
- Tube feeding
- Oral motor feeding problems/developmental disorders
 - Restricted or limited diet related to food aversions/dysphagia
- Hypermetabolic conditions (i.e. cancer/blastoma)

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Failure to Thrive/Feeding Difficulties

- Common formulas (regular, fiber, enteral)
 - Boost Kid Essentials
 - Nutren Junior
 - PediaSure (Peptide requires additional GI implications)
 - Bright Beginnings Soy (FTT + cow's milk protein allergy)

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What is the indicated use for...

Elecare Junior?

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Diagnosis(es) and Indicated Use

- **Malabsorption** - short bowel syndrome, necrotizing enterocolitis, eosinophilic esophagitis (specific nutrients do not have to be documented)

- **Severe/Multiple**

- **Other Indicated Formulas**

- E028 Splash
 - Neocate Infant/Junior
 - PurAmino Infant/Toddler
 - Elecare Infant/Junior
 - Alfamino Infant/Junior



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EleCare® Jr

Nutritionally Complete Amino Acid-Based Medical Food

- A 30 Cal/fl oz, nutritionally complete amino acid-based medical food for children age 1 and older who cannot tolerate intact or hydrolyzed protein.
- EleCare Jr is for the dietary management of protein maldigestion, malabsorption, severe food allergies, short-bowel syndrome, eosinophilic GI disorders, GI-tract impairment, or other conditions in which an amino acid-based diet is required.

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What is the indicated use for...

Peptamen Junior?

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"Google It!"

(or use any preferred search engine)

The screenshot shows a Google search for "Peptamen Jr". The search bar at the top contains "Peptamen Jr" and the Google logo. Below the search bar, there are tabs for "All", "Shopping", "News", "Images", "Videos", and "More". The "Shopping" tab is selected, showing a "Shop for Peptamen Jr on Google" section with five product listings:

- Peptamen Junior Formul... \$188.95 HealthyKin.co. MD-direct Special offer
- Peptamen Jr. Vanilla or Unfl... \$139.85 MD-direct Special offer
- Peptamen Junior Oral Su... \$133.74 FirstOptionMe. MD-direct Special offer
- Peptamen Jr. 1.5 Unflavore... \$185.00 MD-direct Special offer
- Peptamen Junior Formul... \$5.93 Blowout Med...

Below the shopping results, there are four search results from Nestlé Health Science:

- PEPTAMEN JUNIOR® | Nestlé Health Science**
https://www.nestlehealthscience.us/...peptamen-juniorpeptamen-junior...
Complete Peptide-Based Elemental Nutrition for Children Ages 1-13. PEPTAMEN JUNIOR® is a nutritionally complete, easy to digest and easy to absorb...
- PEPTAMEN JUNIOR® 1.5 | Nestlé Health Science**
https://www.nestlehealthscience.us/...peptamen-juniorpeptamen-junior...
PEPTAMEN JUNIOR® 1.5 offers complete peptide-based nutrition for children ages 1-13 with impaired GI function.
- PEPTAMEN JUNIOR® FIBER | Nestlé Health Science**
https://www.nestlehealthscience.us/...peptamen-juniorpeptamen-junior-f...
PEPTAMEN JUNIOR® with Fiber is a nutritionally complete, easy to digest and absorb fiber-containing formula to help support the nutritional needs of children...
- PEPTAMEN JUNIOR® WITH PREBIO | Nestlé Health Science**
https://www.nestlehealthscience.us/...peptamen-juniorpeptamen-junior...
PEPTAMEN JUNIOR® WITH PREBIO is a nutritionally complete, easy to digest and absorb fiber-containing formula to help support the nutritional needs of...

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Nestle Health Science / Brands / Peptamen Junior

Share on:   



PEPTAMEN JUNIOR®

PEPTAMEN is the preferred formula
Among those who had a preference*, more Registered Dietitians prefer Peptamen Junior® over PediaSure® Peptide for GI Impaired patients.

- For the nutritional management of children ages 1 – 13 with impaired GI function
- Enzymatically hydrolyzed 100% whey protein to facilitate gastric emptying
- Reformulated to meet the IOM guidelines for calcium & vitamin D
- Contains CalciLock® blend of essential nutrients to help support healthy bone development. CalciLock® is a

To order samples, [click here](#).

“For the nutritional management of children ages 1 – 13 with impaired GI function...”

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Summary/Highlights

- Medical diagnoses must be specific and consistent with the formula requested and professional assessment
- The nutrient composition of the formula should also be considered aside from the manufacture’s indicated use
- General and non-specific diagnoses require additional documentation
- Diagnosed symptoms require a documented underlying condition

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Summary/Highlights

- A soy formula trial is not required for the issuance of a protein hydrolysate formula
- A protein hydrolysate formula may be issued with the diagnosis of GERD and documented failure of a rice-added formula
- Multiple allergies must be specified, malabsorbed nutrients do not
- The Infant Formula Algorithm and available manufacturer product information can be useful references when authorizing the issuance of special formulas

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Thank You for Your Participation!

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Formula Algorithm for Infants on Georgia WIC Resource Guide
Stanley Cohen, MD, FAAP and Kyla Crane, RDN, LD

Table 2 Pre Term Infant
on other side →

Table 1 Term Infant

Tier	Formula Category	WICApproved Formula*	Manufacturer	Form	Size	Composition	Medical Documentation Required	Indication/ICD-10
Tier 1	"Routine" Cow's Milk Based	Gerber Good Start Gentle	Nestle Nutrition	Powder	12.7 oz.	20 cal per fl. oz., 100% Whey protein partially hydrolyzed, lactose, prebiotics, corn maltodextrin, palm olein, soy oil, coconut oil, high oleic safflower oil or high oleic sunflower oil, prebiotics, DHA/ARA	No	Healthy term infants who are not exclusively breastfed
				Concentrate	12.1 oz.			
				Ready to Feed	33.8 oz. (4-8.45 oz.)			
Tier 2	Soy	Gerber Good Start Soy	Nestle Nutrition	Powder	12.9 oz.	20 cal per fl. oz., Milk free, Lactose free, hydrolyzed soy protein isolate, corn maltodextrin, palm olein, soy oil, coconut oil, high oleic safflower oil or high oleic sunflower oil, DHA/ARA	No	Parental Request Kosher and Halal Vegetarian/Vegan Families Cow's milk allergy or intolerance/Z91.011 Lactose Intolerance/E73.9 Galactosemia/E7421
				Concentrate	12.1 oz.			
				Ready to Feed	33.8 oz. (4-8.45 oz.)			
	Rice Starch	Enfamil AR	Mead Johnson Nutrition	Powder	12.9 oz.	20 cal per fl. oz., Whey 20%, Casein 80%, lactose, rice starch, corn maltodextrin, prebiotics, palm oil, soy oil, coconut oil, high oleic sunflower oil, prebiotics DHA/ARA	Yes	In order for either of these non-contract rice added formulas to be provided by WIC, the following 2 conditions must be met: Diagnosis of Gastroesophageal reflux disease (GERD)/K21.0, K21.9 AND one of the following underlying conditions: Pneumonia/J690, Tube feed/Z97.8, GERD Surgery (Fundoplication/Z98.89), Poor weight gain/R62.51, Weight loss R63.4, and Drop of at least one weight channel on growth chart. Note: If weights are not provided, then weight will be obtained at the WIC clinic.
				Ready to Feed	2 oz.			
					8 oz.			
			32 oz.					
Tier 3	Casein Hydrolysate	Gerber Extensive HA	Nestle Nutrition	Powder	14.1 oz.	20 cal per fl. oz., extensively hydrolyzed, hypoallergenic 100% whey protein, 49% MCT, 90% corn maltodextrin, Probiotic B. lactis, DHA	Yes	Cow's milk allergy or intolerance/Z91.011 Soy protein allergy or intolerance/Z91.018 Food protein-induced Enterocolitis (FPIES)/K52.21
		Nutramigen	Mead Johnson Nutrition	Concentrate	13 oz.	20 cal per fl. oz., extensively hydrolyzed, hypoallergenic lactose free, corn syrup solids, modified corn starch, palm olein, soy oil, coconut oil, high oleic sunflower oil, DHA		
				Ready to Feed	2 oz.			
					32 oz.			
		Nutramigen with Enflora LGG	Mead Johnson Nutrition	Powder	12.6 oz.	Same composition as Nutramigen with Probiotic added (Only in powdered form)		
			Similac Alimentum	Abbott Nutrition	Powder	12.1 oz.		
	Ready to Feed	8 oz.						
				32 oz.				
Extensively Hydrolyzed Casein Containing MCT Oil	Pregestimil	Mead Johnson Nutrition	Powder	1 lb.	20 cal per fl. oz., extensively hydrolyzed, hypoallergenic, lactose free, 55% MCT oil, corn syrup solids, dextrose, modified corn, DHA/ARA	Yes	Malabsorption/K90.4	
			Ready to Feed	2 oz.				
Tier 4	Amino Acid Elemental	Alfamino Infant	Nestle Nutrition	Powder	14.1 oz.	20 cal per fl. oz., hypoallergenic, free amino acid formula, lactose-free and gluten-free, fat blend containing MCT, DHA/ARA	Yes	Short bowel syndrome/K91.2 Necrotizing enterocolitis/P77.9 Eosinophilic esophagitis/K20.0 Severe allergy to cow's milk or intolerance/ Z91.011 with failure to Tier 3 formula Multiple food protein intolerance/K52.21 GI impairment Malabsorption/K90.4
		EleCare Infant	Abbott Nutrition	Powder	14.1 oz.	20 cal per fl. oz., amino acids, Lactose, sucrose, soy, and gluten-free, hypoallergenic, 33% MCT, DHA/ARA		
		Neocate Infant DHA/ARA	Nutricia	Powder	14 oz.	20 cal per fl. oz., hypoallergenic, amino acids, lactose, sucrose, soy, and gluten-free, 33% MCT, DHA/ARA		
		PurAmino	Mead Johnson Nutrition	Powder	14.1 oz.	20 cal per fl. oz., hypoallergenic 100% free amino acids, corn syrup solids, 33% MCT Oil, DHA/ARA		

*State WIC agencies are required by law to competitively bid infant formula rebate contracts with formula manufacturers in which the manufacturers provide a rebate for formula purchased by WIC participants. This translates into more women, infants, and children who can receive WIC benefits. The current WIC Formula Rebate Contract is with Nestle Nutrition. **The following formulas are rebated and DO NOT require Medical Documentation: Gerber Good Start Gentle, Gerber Good Start Soy, and Gerber Good Start Soothe.** Although Lactose Reduced formulas are not included in the Formula Algorithm due to the diagnosis being rare in infancy, Gerber Good Start Soothe is a lactose reduced (30%) formula that is rebated and included as a Georgia WIC Approved formula.

Table 2 Pre Term Infant

Category	WIC Approved Product	Manufacturer	Form	Size	Composition	Medical Documentation Required	Indication/ICD-10
Human Milk Fortifier	Enfamil Human Milk Fortifier Acidified Liquid	Mead Johnson Nutrition	Liquid	5mL vial	Commercially sterile liquid, contains milk & soy ingredients	Yes	Intended for breast-fed babies who were born prematurely or with a low birth weight as a nutritional supplement added to preterm breast milk Prematurity/Low Birth Weight P07.2, P07.3, P07.10, P07.14-P07.18
	Similac Human Milk Fortifier	Abbott Nutrition	Powder ¹	0.9g	Powdered, contains milk & soy ingredients	Yes	Intended for breast-fed babies with a low birth weight as a nutritional supplement added to preterm milk Low Birth Weight P07.2, P07.3, P07.10, P07.14-P07.18
Premature Formulas Pre-Discharge (24 cal with increased amounts of protein, vitamins & minerals) ²	Enfamil Premature 20, 24, 30	Mead Johnson Nutrition	Ready to Feed	2 oz.	Whey protein 60%, casein 40%; corn syrup solids, lactose, 40% of fat is MCT oil, increased protein, calcium, phosphorus, & vitamin D	Yes	Preterm/low birth weight infants with increased calorie, protein, vitamin, & mineral requirements. Prematurity/Low Birth Weight P07.2, P07.3, P07.10, P07.14-P07.18
	Similac Special Care 20, 24, or 30 with Iron	Abbott Nutrition	Ready to Feed	2 oz.	Nonfat milk, whey protein concentrate, corn syrup solids lactose, 50% of fat is MCT, Lutein, increased protein, calcium, phosphorus, & vitamin D	Yes	Preterm/low birth weight infants with increased calorie, protein, vitamin, & mineral requirements. Prematurity/Low Birth Weight P07.2, P07.3, P07.10, P07.14-P07.18
Transitional Formulas Post-Discharge (22 cal with increased amounts of protein, vitamins & minerals) ²	Enfamil Enfacare	Mead Johnson Nutrition	Powder ¹	12.8 oz.	Nonfat milk, whey protein concentrate, corn syrup solids, lactose, MCT oil, Lutein, increased calcium, phosphorus, & vitamin D	Yes	Preterm/low birth weight infants with increased calorie, vitamin, & mineral requirements. Prematurity/Low Birth Weight P07.2, P07.3, P07.10, P07.14-P07.18
			Ready to Feed	2 oz.			
				8 oz.			
	Similac Neosure	Abbott Nutrition	Powder ¹	13.1 oz.	Nonfat milk, whey protein concentrate, corn syrup solids, lactose, MCT oil, Lutein, increased calcium, phosphorus, & vitamin D	Yes	Preterm/low birth weight infants with increased calorie, vitamin, & mineral requirements. Prematurity/Low Birth Weight P07.2, P07.3, P07.10, P07.14-P07.18
			Ready to Feed	2 oz.			
				1 qt.			

1 Powdered formulas are not sterile & should not be fed to premature infants or infants who might have immune problems unless directed and supervised by a physician. Taylor, CJ Health Professionals Letter on Enterobacter Sakazakii Infections Associated with the Use of Powdered (Dry) Infant Formulas in Neonatal Intensive Care Units. April 11, 2002. US Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements.

Available at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/InfantFormula/AlertsSafetyInformation/ucm111299.htm>

2 To bridge the change from preterm to standard infant formulas in formula-fed infants, “transitional” formulas with intermediate nutrient density have been developed for feeding the preterm infant as weight approaches 2000 g and the time of hospital discharge nears. These formulas may be mixed to 22 or 24 kcal/oz. In general, there is a paucity of data on what to feed the preterm infant after hospital discharge, especially if the goal is to achieve “catch-up” growth. How fast these preterm infants (and especially those born small for gestational age) should demonstrate catch-up growth after hospital discharge is an area of critical need of research given the increased risk of these infants developing metabolic syndrome later in life.

Pediatric Nutrition Handbook, AAP 2009.

Note - Soy protein-based formulas are not recommended for preterm infants. American Academy of Pediatrics, Committee on Nutrition. Use of Soy-Protein-Based Formulas in Infant Feeding. Pediatrics. 2008. Vol 121/Issue 5

Visit wic.ga.gov for additional Georgia WIC resources.

Adapted from Source: Nutrition4Kids.com Stanley Cohen, MD and Bailey Koch, RD, CSP

Revised 2016