



Good food, Good life

Nestlé Canada Inc.
25 Sheppard Avenue West
North York, ON
M2N 6S6
T +1(416) 218 3030

June 15, 2022

Dear Pharmacists:

As you know, in Canada, we are experiencing a shortage of infant formulas designed for babies with food allergies and certain medical conditions. Our hearts go out to all the parents and families who are affected by this shortage and situation.

While we do not sell this specialty formula in Canada, through our collaborative efforts with Health Canada and our Nestlé US counterparts, we have been able to temporarily import a limited supply of Nestlé's Gerber Good Start Extensive HA™, an extensively hydrolyzed infant formula sold in the US, to help alleviate the current shortage situation.

While supplies last, you can order Nestlé's Gerber Good Start Extensive HA™ based on parent request for extensively hydrolyzed infant formula through your current infant formula distributor based on availability from your distribution centre. This controlled distribution will help ensure availability of product for the infants who require this type of specialty infant formula. When you receive an order and deliver it to parents, please ensure to print and hand out the documentation at the following Health Canada link that lists all critical product information in French: [gerber-extensive-ha.pdf \(canada.ca\)](#)

An English version of the label is available at the following Health Canada link: [English label for Gerber® Good Start® Extensive HA® For Milk Intolerance & Allergy - Canada.ca](#)

Health Canada has published information for Health Care Providers and parents that outlines the situation and offers guidance for use of important products such as Nestlé's Gerber Good Start Extensive HA™. This information can be found at the following link: [shortage.pdf \(canada.ca\)](#).

A national clinical decision tree entitled, "Use of Specialized Infant Formula During a Shortage" has been recently developed to support health care providers across the country guide treatment decisions, and support families and caregivers to make appropriate formula choices while rationing the use of specialized infant formulas. Health Canada facilitated bringing together experts from a broad community of healthcare stakeholders for its development, including: Canadian Pediatric Society, Canadian Pharmacists Association, Food Allergy Canada, Canadian Society of Allergy and Clinical Immunology, Dietitians of



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Canada, Hospital for Sick Children and McMaster Children's Hospital. This tool offers specific guidance to health care providers when counseling families, discussing safe alternatives, and conserving limited national supplies of specialized formulas. This decision tree is attached to this letter. It has also been disseminated directly to members of the Health Care Professional Associations that helped in its development.

Product information for Nestlé's Gerber Good Start Extensive HA™ for Health Care Professionals is also attached to this letter.

If you have questions or require further information please email us:
nestlespecialtyformula@ca.nestle.com

Thank you for your support.

Sincerely,

Alison McLean

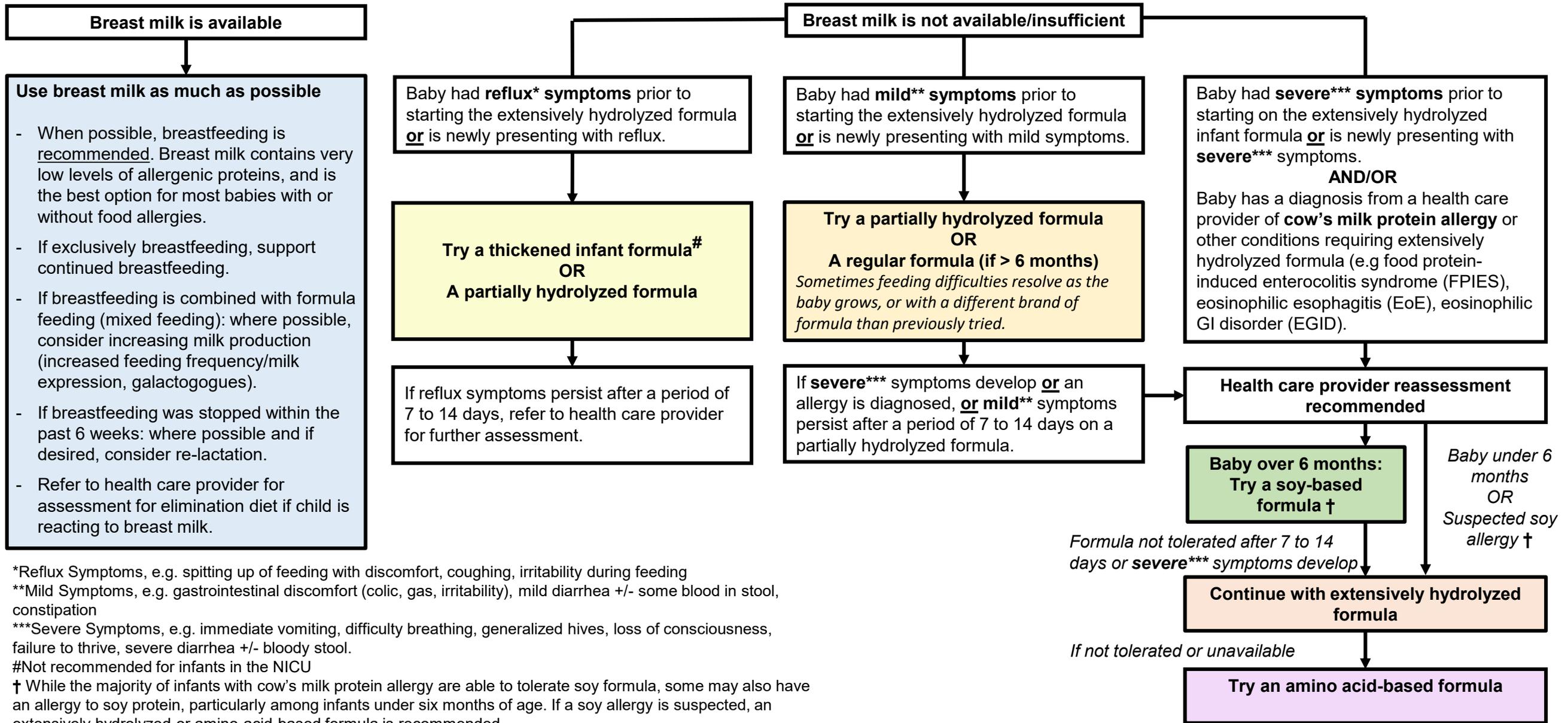
President, Nestlé Nutrition

Andrea Papamandjaris, PhD

Director, Medical Channel and Regulatory, Scientific Affairs

Use of Specialized Infant Formula during a Shortage

Given the shortage of hypoallergenic (extensively hydrolyzed and amino acid-based) infant formula, the following decision tree aims to support health care providers in temporarily guiding parents and caregivers toward the most appropriate choices, while reserving supply of specialized products for infants with medical conditions requiring these formulas. **These recommendations only apply during this period of shortage and are not intended to replace clinical judgement.** Parents and guardians should consult with a health care provider regarding their child's symptoms and the need to switch to a different formula. See page 2 for list of alternate formulas.



*Reflux Symptoms, e.g. spitting up of feeding with discomfort, coughing, irritability during feeding

**Mild Symptoms, e.g. gastrointestinal discomfort (colic, gas, irritability), mild diarrhea +/- some blood in stool, constipation

***Severe Symptoms, e.g. immediate vomiting, difficulty breathing, generalized hives, loss of consciousness, failure to thrive, severe diarrhea +/- bloody stool.

#Not recommended for infants in the NICU

† While the majority of infants with cow's milk protein allergy are able to tolerate soy formula, some may also have an allergy to soy protein, particularly among infants under six months of age. If a soy allergy is suspected, an extensively hydrolyzed or amino-acid-based formula is recommended

This document has been developed by a group of Registered Dietitians and reviewed by representatives of: 1) the Canadian Pediatric Society – Nutrition and Gastroenterology Committee, 2) the Hospital for Sick Children - Department of Clinical Dietetics, Division of Gastroenterology, Hepatology & Nutrition and Division of Immunology and Allergy, 3) McMaster Children's Hospital - Division of Gastroenterology, Hepatology & Nutrition, Division of Allergy & Immunology and Clinical Dietetics, 4) the Canadian Pharmacists Association, 5) Food Allergy Canada's Healthcare & Scientific Advisory Board, 6) the Canadian Society of Allergy and Clinical Immunology (CSACI), and 7) Dietitians of Canada

Use of Specialized Infant Formula during a Shortage

Given the shortage of hypoallergenic (extensively hydrolyzed and amino acid-based) infant formula, the decision tree on page 1 aims to support health care providers in temporarily guiding parents and caregivers toward the most appropriate choices while reserving supply of these specialized products for infants with medical conditions requiring these formulas. **These recommendations only apply during this period of shortage and are not intended to replace clinical judgment.** Parents and caregivers should consult with a health care provider regarding their child's symptoms and the need to switch to a different formula.

Thickened infant formulas (not suitable for tube feeding or use in NICU):

- Enfamil A+ for Frequent Spit Up (if infant not already on medication for reflux)

Partially hydrolyzed infant formulas, e.g:

- Nestle GoodStart 1, 2 or Plus 1 or Plus 2
- Nestle GoodStart Soothe
- Enfamil A+ Gentlease
- Similac Total Comfort

Partially hydrolyzed formulas for children > 12 months (or earlier at healthcare provider discretion)[§], used for severe medical conditions:

- Peptamen Junior
- PediaSure Peptide

Soy-based infant formulas:

- Similac Isomil with DHA
- Enfamil A+ Soy
- Nestle Good Start Alsoy

Extensively hydrolyzed infant formulas ‡:

- Nutramigen A+, Nutramigen A+ LGG
- Pregestimil A+
- Similac Alimentum

Amino acid-based infant formulas ‡:

- Neocate Infant DHA & ARA
- Puramino A+

Amino acid-based formulas for children > 12 months (or earlier at healthcare provider discretion) ‡ §:

- | | |
|------------------|---------------------|
| - Neocate Junior | - Equacare Jr |
| - Neocate Splash | - Essential Care Jr |
| - Puramino Jr | - Vivonex Pediatric |

Formula Switching Tips

Start gradually: Start by replacing 1/4 of baby's bottle with the new formula, and gradually increase

Be patient: It is normal that infants may take time to adjust to a new formula. Unless severe symptoms occur, continue with trial of new formula for 7-14 days

If breast milk is available, **consider mixing** with formula to improve tolerance

Reminder:

Extensively hydrolyzed formulas are **NOT** recommended for the prevention of food allergies. No formula has proven benefits for allergy prevention.

Important Reminders for Parents and Caregivers:

Do not attempt to make homemade infant formula. Commercial infant formula contains many important nutrients and components that cannot be recreated at home. Homemade infant formula can put an infant's health at risk.

Do not use other formula substitutes such as cow's milk, goat milk, evaporated milk, soy, oat, almond or rice beverages. These drinks are not nutritionally complete. The only beverage infants need is breast milk or infant formula.

Always prepare infant formula according to label directions. **Do not dilute** with extra water or other fluids.

Do not use breast milk from unknown sources or obtained online. Informal milk sharing is also not recommended, however the following resource provides additional guidance on this topic:
<https://cps.ca/documents/position/pasteurized-and-unpasteurized-donor-human-milk>

[§] Products indicated for children 12+ months may be transitioned earlier. Refer to health care provider for assessment.

[‡] Alternate products may become available on an interim basis during the shortage – see Health Canada website for list: <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/policies/interim-policy-importation-sale-infant-formula-human-milk-fortifiers-metabolic-products.html>

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This document provides information related to the import of Gerber® Good Start® Extensive HA® under the Health Canada Interim Policy on the Importation and Sale of Infant Formulas.

Gerber® Good Start® Extensive HA®

Hypoallergenic. Extensively hydrolyzed, iron-fortified infant formula for babies with cow's milk allergy or intolerance and/or fat malabsorption. With 100% whey protein extensively hydrolyzed, probiotic *B. lactis*, MCT, and a lactose-free carbohydrate blend.



- ✓ Meets the AAP hypoallergenicity criteria.^{1,2}
- ✓ Clinically shown to promote adequate growth.³
- ✓ Meets the FDA nutrient specifications for infant formulas in the United States.⁴
- ✓ Included in NASPGHAN table for possible substitutions for recalled formulas.⁵

	Good Start® Extensive HA®	Nutramigen® A+® with LGG®	Nutramigen® A+®	Pregestimil® A+®	Similac® Alimentum®
Appropriate for:					
✓ Cow's milk protein allergy or intolerance	✓	✓	✓	✓	✓
✓ Fat malabsorption	✓	✗	✗	✓	✓
Protein (g/100 mL)* <i>Source</i>	1.76 <i>Extensively hydrolyzed whey</i>	1.9 <i>Extensively hydrolyzed casein, amino acid premix</i>	1.89 <i>Extensively hydrolyzed casein, amino acid premix</i>	1.89 <i>Extensively hydrolyzed casein, amino acid premix</i>	1.86 <i>Extensively hydrolyzed casein, free amino acids</i>
MCT (% total fat)	49%	✗	✗	55%	33%
Probiotics	<i>Bifidobacterium lactis (B. lactis)</i>	<i>Lactobacillus GG® (LGG®)</i>	✗	✗	✗
Carbohydrate blend	Corn maltodextrin, potato starch	Corn syrup solids, modified corn starch	Corn syrup solids, modified corn starch	Corn syrup solids, modified corn starch	Corn maltodextrin, sucrose

Abbreviations: AAP = American Academy of Pediatrics; FDA = Food and Drug Administration; HA = Hypoallergenic; MCT = Medium Chain Triglyceride; NASPGHAN = North American Society for Pediatric Gastroenterology, Hepatology & Nutrition

*Standard dilution

References: 1. American Academy of Pediatrics. Committee on Nutrition. Hypoallergenic infant formulas. *Pediatrics*. 2000;106:346-349. 2. Nowak-Wegrzyn A, et al. *Allergy*. 2019;74(8):1582-1584. 3. Fields D, et al. *Glob Pediatr Health*. 2016;3:1-9. 4. FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements. July 2002. 5. North American Society for Pediatric Gastroenterology, Hepatology & Nutrition. NASGHAN Tools for HCPs Managing Infants and Children Affected by Formula Recall. May 4, 2022. Accessed June 3, 2022. <https://naspghan.org/recent-news/naspghan-tools-for-hcps-affected-by-formula-recall/>

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Gerber® Good Start® Extensive HA®

HYPOALLERGENIC | 0+ MONTHS | POWDER

Extensively hydrolyzed, iron-fortified infant formula for the dietary management of infants with cow's milk protein allergy or intolerance and/or for the dietary management of infants with fat malabsorption.



NUTRITION-AT-A-GLANCE (Standard Dilution)

Energy (kcal/100 mL)	67.5
Protein (g/100 mL) <i>Source</i>	1.76 <i>100% whey extensively hydrolyzed</i>
Fat (g/100 mL) <i>Source</i>	3.4 <i>49% MCT oil, 28% soy oil, 10% high oleic sunflower oil, 6% high 2-palmitic vegetable oil, 5% CITREM, 2% single cell oil</i>
Carbohydrate (g/100 mL) <i>Source</i>	7.4 <i>90% corn maltodextrin, 10% potato starch</i>
DHA (% total fat) <i>Source</i>	0.32 <i>C. Cohnii oil</i>
ARA (% total fat) <i>Source</i>	0.32 <i>M. Alpina oil</i>
Probiotic (CFU/g powder) <i>Source</i>	1 x 10 ⁶ <i>B. lactis</i>
Calcium (mg/100 mL)	61
Iron (mg/100 mL)	1.2
Ca:P ratio	1.4:1
Osmolality (mOsm/kg H ₂ O)	220
Potential Renal Solute Load (mOsm/L)	181

Preparation Instructions

Gerber® Good Start® Extensive HA® requires 1 scoop for 1 fl oz of water:



Gram Weights & Displacement Factors[‡] for Gerber® Good Start® Extensive HA®

Grams powder per scoop	Grams powder per tablespoon	Displacement per scoop, mL	Displacement per gram of powder, mL	Displacement per tablespoon of powder, mL
4.6	8.2	3.3	0.72	5.89

[‡]Values are approximate based on calculated results. Measuring powder by weight yields the most accurate results. If an exact dilution is not required and powder is measured by volume, powder should be level and unpacked. As with any powdered infant formula product, use with immune compromised infants is not recommended.