

Update on shortage of specialized infant formula

Importation of United States-labelled Nutramigen A+ Concentrate Infant Formula due to shortage of specialized infant formula

Due to the shortage of extensively hydrolyzed infant formulas in Canada, Health Canada has allowed the importation from the United States of Mead Johnson's **Nutramigen A+ Concentrate Infant Formula**. **This product is to be kept behind the counter of the pharmacy.**

Note: Supply of this imported **Nutramigen A+ Concentrate Infant Formula** is expected to arrive in Alberta the week of June 13, 2022, and will be distributed through wholesalers, such as McKesson.

Temporary benefit added to the *Alberta Human Services Drug Benefit Supplement (HSDBS)*

To ensure coverage is provided for this product for members of eligible government-sponsored drug programs, **a temporary Product Identification Number (PIN) has been assigned to (US) Nutramigen A+ Concentrate Infant Formula (PIN: 0999300).**

As of June 13, 2022, all claims for the above product will be adjudicated to the price of **\$0.0217** per millilitre.

Mead Johnson's imported **Nutramigen A+ Concentrate Infant Formula** carton and package leaflet in French and English have been published by Health Canada and are available at the following links:

- English: canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/policies/interim-policy-importation-sale-infant-formula-human-milk-fortifiers-metabolic-products/enfamil-nutramigen.html
- French: canada.ca/fr/sante-canada/services/aliments-nutrition/legislation-lignes-directrices/politiques/politique-temporaire-importation-vente-preparations-nourrissons-fortifiants-lait-humain-produits-metaboliques/enfamil-nutramigen.html

Alberta Blue Cross will continue to monitor the availability of the shorted products and potential alternatives, in addition to working with other provinces and territories, manufacturers and Health Canada to address this shortage and minimize the impact on Albertans.

Background

The closure of a large infant formula manufacturing plant in the United States (manufacturer of Similac® Alimentum®, an extensively hydrolyzed formula) has resulted in a global shortage of infant formula for babies with allergies and certain medical conditions.

Note: **There is no current shortage of regular infant formula in Canada.** However, there is a shortage of infant formula for infants with food allergies and certain medical conditions. This includes extensively hydrolyzed and amino acid-based formulas.

To help mitigate the impact of this shortage, Health Canada has recommended that the Canadian Food Inspection Agency (CFIA) temporarily exercise enforcement discretion with respect to certain labelling and composition requirements related

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to the importation and sale of certain infant formulas. These products have been approved by a foreign regulatory authority or are allowed to be sold in foreign jurisdictions that have high quality and manufacturing standards similar to Canada. Infant formulas from other countries not on Health Canada's approved list under the interim policy on the importation and sale of infant formulas should not be used.

Please be advised that on June 4, 2022, the impacted manufacturing plant was re-opened. Infant formula will gradually become available from this plant in the coming months, starting with specialized infant formula.

Pharmacists and other health care professionals are reminded of the following:

- Supply of this imported product should be conserved for those infants with a medical indication for this **extensively hydrolyzed formula. This includes Cow's Milk Protein Allergy (CMPA) and severe gastrointestinal intolerance (physician guidance may be required) to standard infant formula.**
- An attempt should be made to provide equitable amounts of formula to all families. When possible, please limit supply dispensed for extensively hydrolyzed and amino acid-based formulas for this duration of the shortage.

Note: Please use the link below to access the document *"Typical formula consumption amounts for Healthy Term Infants"*, created by Alberta Health Services (AHS), to provide pharmacists with a tool to estimate how much of each formula an infant would typically require. This may help when rationing the use of specialty infant formulas.

albertahealthservices.ca/assets/info/nutrition/if-nfs-typical-formula-consumption-healthy-term-infants.pdf

- The shortage of extensively hydrolyzed infant formulas has placed additional pressure on the limited supply of amino acid-based formulas available. **Amino acid-based formulas are critical for babies at risk of very serious allergic (anaphylactic) reactions. It is therefore critical that consumption of these products be prescribed or recommended by a health care professional for babies who require them.**

Additional resources

- To help facilitate communication with health care professionals about the infant formula shortage in Alberta, a new Alberta Health Services webpage has been launched. Please check this page regularly for updated documents and available links.
 - **Infant Formula Shortage**—Information for Health Professionals
albertahealthservices.ca/nutrition/Page18039.aspx
- Health Canada has published additional information related to this shortage, which can be found using the following links:
 - **Information for families during the shortage of formula for babies with food allergies**
canada.ca/en/health-canada/services/infant-care/infant-formula/shortage.html
 - **Public advisory—Shortage of infant formulas for babies with food allergies: what you should know and do**
recalls-rappels.canada.ca/en/alert-recall/shortage-infant-formulas-babies-food-allergies-what-you-should-know-and-do

For assistance with benefit or claim inquiries, please contact an Alberta Blue Cross Pharmacy Services Provider Relations contact centre representative at

780-498-8370 (Edmonton and area)

403-294-4041 (Calgary and area)

1-800-361-9632 (toll free)

FAX 780-498-8406 (Edmonton and area)

FAX 1-877-305-9911 (toll free)

Alberta Blue Cross offers online access to current Pharmacy Benefacts and supplemental claiming information to assist with the submission of your direct bill drug claims.

Visit ab.bluecross.ca/providers/pharmacy-home.php

