

June 13th, 2022



Health Canada Interim Policy to address extensively hydrolyzed formula short supply: Approval to launch Nutramigen® Liquid Concentrate

Dear Valued Healthcare Professional/Customer,

As communicated by Reckitt/Mead Johnson Nutrition on May 10th, 2022, the recent recall and plant closure of a competitor infant formula manufacturer has resulted in a shortage of extensively hydrolyzed infant formula in Canada. Reckitt/Mead Johnson Nutrition is now able to import Nutramigen® Liquid Concentrate from the United States to support parents of infants with cow's milk protein allergy (CMPA) and colic due to CMPA.

Health Canada is recommending that the Canadian Food Inspection Agency (CFIA) temporarily exercise enforcement discretion to allow the importation of certain products into Canada. This includes products that, while not fully complying with Canadian labelling and composition requirements, 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.

You can view Health Canada's interim policy for more details through this link : <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>

To address the shortage of extensively hydrolyzed infant formula the following product will be made available in limited quantity at the pharmacy counter of most pharmacies for you to prescribe to your parents of infants with CMPA. It will be available the week of June 20th, 2022, until a date to be confirmed in collaboration with Health Canada. The product will be restricted to the following wholesaler: McKesson. Formulary coverage has been approved by the *Régie de l'assurance médicament du Québec*. We are currently working to request coverage for Nutramigen Liquid Concentrate on various public drug benefit programs. More information will be provided shortly once the product is formally listed.

Product	Format	Unit Size	Units per Case	Approximate Product Yield at Normal Dilution	Shelf Life
Nutramigen® Liquid Concentrate	Concentrate (Sterile)	384 mL	12 cans	770 mL (3 bottles x 237 mL)	12 Months

The prescription of Nutramigen® should be exclusively reserved for infants who require an extensively hydrolyzed infant formula for the management of CMPA and colic due to CMPA. Infants often experience tolerance issues as their digestive systems are still developing, Reckitt/Mead Johnson Nutrition offers other formula options to address common feeding issues.

IMPORTANT NOTE:

- Following the procedures established by the Interim Policy, Reckitt/Mead Johnson Nutrition will be shipping the above listed SKU with the original English US label.
- See **Appendix 1** for a modified version of the English US label with the Canadian Customer Resource Centre, and a French translation of the English US label.
- **It is required that a copy of the updated English and French translation of the US label be distributed with each product dispensed to parents. Copies of this label can be printed directly from medical.enfamil.ca/articles/health-canada-interim-policy-launch-nutramigen-concentrate**
- **Please note that this product is a concentrate and needs to be diluted with water to prepare calorific feed as per each infant's nutritional requirements. Please refer to the preparation instructions and product information details on the US label or at medical.enfamil.ca/articles/health-canada-interim-policy-launch-nutramigen-concentrate**

We would like to reassure you that Reckitt/Mead Johnson Nutrition has made it our top priority to support parents and healthcare providers nourish these vulnerable infants. If you have any questions, please do not hesitate to contact your Reckitt/Mead Johnson Nutrition Representative.

Thank you for your collaboration and understanding during these difficult times.

Sincerely,
Carole Aylwin
Director Healthcare Sales
Reckitt/Mead Johnson Nutrition, Canada



HYPOALLERGENIC INFANT FORMULA WITH IRON

0-12 months
13 fl oz (384 mL)

BRAIN BUILDING DHA

for FOOD ALLERGIES INCLUDING COW'S MILK ALLERGY

FAST COLIC RELIEF¹

NO ARTIFICIAL GROWTH HORMONES²

THIS IS A Concentrate
Must Add Water

DOES NOT USE TABLE SUGAR³

Instructions for preparation & use

Your baby's health depends on carefully following the instructions below. Proper hygiene, preparation, dilution, use and storage are important when preparing infant formula. Use as directed by your baby's doctor.

Ask your baby's doctor about the need to use cooled, boiled water for mixing and the need to boil clean utensils, bottles, and nipples in water before use.



1. Wash hands thoroughly with soap and water before preparing formula.



2. Clean can lid, **SHAKE CAN WELL**, and open.



3. Pour desired amount of water into the bottle. Add an **equal** amount of concentrated liquid. **Shake or stir well.**

WARNING: Do not use a microwave oven to warm formula. Serious burns may result.

Failure to follow these instructions could result in severe harm. Opened cans and prepared formula can spoil quickly. Either feed immediately or cover and store in refrigerator at 35-40°F (2-4°C) for no longer than 48 hours. Do not use opened can and/or prepared formula if they are unrefrigerated for more than a total of 2 hours. Do not freeze prepared formula. After feeding begins, use formula within one hour or discard.

Storage: Store unopened cans at room temperature. Avoid excessive heat. Do not freeze. Nutramigen® does not look or taste like milk or soy formulas. Product may separate. Shake well before feeding.

USE BY DATE ON TOP OF CAN

Nutramigen is a nutritionally complete, hypoallergenic, lactose-free formula for newborns and infants who have food allergies including cow's milk allergy. It is also proven[#] to deliver fast relief from severe crying/colic due to cow's milk allergy – often within 48 hours.

[#]Studied before the addition of DHA and ARA ingredients

If you have a question, we are here for you. Call us toll free: 1-800 361-6323, or visit Enfamil.ca

NUTRIENTS

(Normal Dilution); per 100 Calories (5 fl oz)

PROTEIN	g.....	2.8
FAT	g.....	5.3
CARBOHYDRATE	g.....	10.3
WATER	g.....	133
LINOLEIC ACID	mg.....	780
VITAMINS		
A.....	IU.....	300
D.....	IU.....	50
E.....	IU.....	2
K.....	mcg.....	9
THIAMIN (B1).....	mcg.....	80
RIBOFLAVIN (B2).....	mcg.....	90
B6.....	mcg.....	60
B12.....	mcg.....	0.3
NIACIN.....	mcg.....	1000
FOLIC ACID (FOLACIN).....	mcg.....	16
PANTOTHENIC ACID.....	mcg.....	500
BIOTIN.....	mcg.....	3
C (ASCORBIC ACID).....	mg.....	12
CHOLINE.....	mg.....	24
INOSITOL.....	mg.....	24
MINERALS		
CALCIUM.....	mg.....	94
PHOSPHORUS.....	mg.....	52
MAGNESIUM.....	mg.....	8
IRON.....	mg.....	1.8
ZINC.....	mg.....	1
MANGANESE.....	mcg.....	25
COPPER.....	mcg.....	75
IODINE.....	mcg.....	15
SELENIUM.....	mcg.....	2.8
SODIUM.....	mg.....	47
POTASSIUM.....	mg.....	110
CHLORIDE.....	mg.....	86

INGREDIENTS: Water (75%), Corn syrup solids (10%), Vegetable oil (7%) (palm olein, soy, coconut, and high oleic sunflower oils), Casein hydrolysate⁴ (milk) (4%), Modified corn starch (4%), and less than 2%: Mortierella alpina oil⁵, Schizochytrium sp. oil⁶, Citric acid, Calcium phosphate, Potassium chloride, Calcium carbonate, Potassium citrate, Sodium citrate, Magnesium oxide, Ferrous sulfate, Zinc sulfate, Cupric sulfate, Manganese sulfate, Potassium iodide, Sodium selenite, Ascorbic acid, Vitamin E acetate, Niacinamide, Calcium pantothenate, Vitamin A palmitate, Thiamin hydrochloride, Riboflavin, Vitamin B₆ hydrochloride, Vitamin D₃, Folic acid, Vitamin K₁, Biotin, Vitamin B₁₂, Choline chloride, Inositol, Carrageenan, Taurine, L-cystine, L-tyrosine, L-tryptophan, L-carnitine.

This exclusive formula is available only from the Enfamil® brand. THIS FORMULA IS NOT SOLD TO ANY RETAILER AS A STORE BRAND

MEAD JOHNSON & COMPANY, LLC, EVANSVILLE, IN 47721 U.S.A
©2022 Mead Johnson & Company, LLC

¹ Within 48 hours; due to Cow's Milk Allergy

² No significant difference has been shown between milk ingredients derived from rbST-treated and non-rbST treated cows

³ Sucrose as a source of carbohydrate

⁴ MODIFIED TO BE BETTER TOLERATED IN MILK-ALLERGIC BABIES

⁵ A SOURCE OF ARACHIDONIC ACID (ARA)

⁶ SOURCE OF DOCOSAHEXAENOIC ACID (DHA)



PRÉPARATION HYPOALLERGÉNIQUE POUR NOURRISSONS ENRICHIE DE FER

La marque numéro 1 recommandée par les pédiatres

0 à 12 mois
13 oz liq (384 ml)

ADH POUR LE DÉVELOPPEMENT DU CERVEAU

pour les ALLERGIES ALIMENTAIRES, Y COMPRIS L'ALLERGIE AU LAIT DE VACHE

SOULAGEMENT RAPIDE DES COLIQUES¹

AUCUNE HORMONE DE CROISSANCE ARTIFICIELLE²

CECI EST UN CONCENTRÉ

Ajouter de l'eau

NE CONTIENT PAS DE SUCRE DE TABLE³

Directives de préparation et d'utilisation

Suivez attentivement le mode d'emploi ci-dessous, car la santé de votre bébé en dépend. Il est important de respecter les normes appropriées en matière d'hygiène, de préparation, de dilution, d'usage et d'entreposage au moment d'apprêter la préparation pour nourrissons. Utilisez selon les directives du médecin de votre bébé.

Consultez le médecin de votre bébé quant au besoin d'utiliser de l'eau bouillie et refroidie pour effectuer le mélange et de faire bouillir des ustensiles, biberons et tétines propres dans l'eau avant leur utilisation.



1. Lavez-vous bien les mains avec du savon et de l'eau avant d'apprêter la préparation.



2. Nettoyez le couvercle du contenant. **AGITEZ BIEN** le contenant avant de l'ouvrir.



3. Versez la quantité d'eau appropriée dans le biberon. Ajoutez une quantité égale de liquide concentré. **AGITEZ OU MÉLANGEZ BIEN.**

MISE EN GARDE : Ne pas utiliser de four à micro-ondes pour chauffer la préparation, car celle-ci risque de causer de graves brûlures.

Le non-respect de ces directives pourrait avoir de graves conséquences. Une fois apprêtée, la préparation pour nourrissons est hautement périssable. Servir immédiatement ou couvrir et conserver au réfrigérateur entre 2 et 4 °C (35 et 40 °F) pendant un maximum de 24 heures. Ne pas utiliser la préparation apprêtée si elle est demeurée plus de 2 heures au total sans être réfrigérée. Ne pas congeler la préparation apprêtée. Après le début de la tétée, jeter toute préparation non consommée après une heure.

Conservation : Conserver les boîtes non ouvertes à la température ambiante. Éviter la chaleur excessive. Ne pas congeler.

Nutramigen® n'a ni l'apparence ni le goût des préparations à base de lait ou de soya. Le produit peut se séparer. Bien agiter avant de servir.

UTILISER AVANT LA DATE INDIQUÉE SUR LE DESSUS DE LA BOÎTE

Nutramigen est une préparation nutritionnelle complète, hypoallergénique et sans lactose pour les nouveau-nés et les nourrissons qui présentent des allergies alimentaires, y compris une allergie au lait de vache. Il est également prouvé[#] qu'elle soulage rapidement les pleurs et les coliques graves attribuables à l'allergie au lait de vache, souvent dans les 48 heures.

[#]Étude menée avant l'ajout d'ingrédients contenant de l'ADH et de l'ARA

Si vous avez des questions, c'est avec plaisir que nous y répondrons. Appelez-nous au numéro sans frais 1-800 361-6323, ou visitez le site Web Enfamil.ca

NUTRIMENTS

(Dilution normale); par portion de 100 calories (5 oz liq.)

PROTÉINES.....	g.....	2,8
LIPIDES.....	g.....	5,3
GLUCIDES.....	g.....	10,3
EAU.....	g.....	133
ACIDE LINOLÉIQUE.....	mg.....	780
VITAMINES		
A.....	U.I.....	300
D.....	U.I.....	50
E.....	U.I.....	2
K.....	mcg.....	9
THIAMINE (B ₁).....	mcg.....	80
RIBOFLAVINE (B ₂).....	mcg.....	90
B ₆	mcg.....	60
B ₁₂	mcg.....	0,3
NIACINE.....	mcg.....	1000
ACIDE FOLIQUE (FOLACINE).....	mcg.....	16
ACIDE PANTOTHÉNIQUE.....	mcg.....	500
BIOTINE.....	mcg.....	3
C (ACIDE ASCORBIQUE).....	mg.....	12
CHOLINE.....	mg.....	24
INOSITOL.....	mg.....	24
MINÉRAUX		
CALCIUM.....	mg.....	94
PHOSPHORE.....	mg.....	52
MAGNÉSIUM.....	mg.....	8
FER.....	mg.....	1,8
ZINC.....	mg.....	1
MANGANÈSE.....	mcg.....	25
CUIVRE.....	mcg.....	75
IODE.....	mcg.....	15
SÉLÉNIUM.....	mcg.....	2,8
SODIUM.....	mg.....	47
POTASSIUM.....	mg.....	110
CHLORURE.....	mg.....	86

INGRÉDIENTS : Eau (75 %), Extraits secs de sirop de maïs (10 %), Huile végétale (7 %) (oléine de palme, soya, huile de noix de coco, huile de tournesol à haute teneur en acide oléique), Hydrolysate de caséine⁴ (lait) (4 %), Amidon de maïs modifié (4 %) et moins de 2 % des substances suivantes : Huile de *Mortierella alpina*⁵, Huile de *Schizochytrium* sp.⁶, Acide citrique, Phosphate de calcium, Chlorure de potassium, Carbonate de calcium, Citrate de potassium, Citrate de sodium, Oxyde de magnésium, Sulfate ferreux, Sulfate de zinc, Sulfate cuivrique, Sulfate de manganèse, Iodure de potassium, Sélénite de sodium, Acide ascorbique, Acétate de vitamine E, Niacinamide, Pantothénate de calcium, Palmitate de vitamine A, Chlorhydrate de thiamine, Riboflavine, Chlorhydrate de vitamine B₆, Vitamine D₃, Acide folique, Vitamine K₁, Biotine, Vitamine B₁₂, Chlorure de choline, Inositol, Carraghénane, Taurine, L-cystine, L-tyrosine, L-tryptophane, L-carnitine.

Cette préparation exclusive est disponible uniquement auprès de la marque Enfamil®. CETTE PRÉPARATION N'EST VENDUE À AUCUN DÉTAILLANT EN TANT QU'UNE MARQUE DE DISTRIBUTEUR

MEAD JOHNSON & COMPANY, LLC EVANSVILLE, IN 47721 É.-U.

©2022 Mead Johnson & Company, LLC

¹ Dans les 48 heures si attribuables à une allergie au lait de vache

² Aucune différence significative n'a été démontrée entre les ingrédients du lait provenant de vaches traitées par STbr et de vaches non traitées par STbr

³ Saccharose comme source de glucides

⁴ MODIFIÉ POUR ÊTRE MIEUX TOLÉRÉ CHEZ LES BÉBÉS ALLERGIQUES AU LAIT

⁵ SOURCE D'ACIDE ARACHIDONIQUE (ARA)

⁶ SOURCE D'ACIDE DOCOSAHEXANOÏQUE (ADH)