PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

Addnutriv™

Trace Elements for Injection

Intravenous Solution

Chromium	10 mcg / 10 mL
Copper	380 mcg / 10 mL
Iron	1100 mcg / 10 mL
Manganese	55 mcg / 10 mL
Iodine	130 mcg / 10 mL
Fluoride	950 mcg / 10 mL
Molybdenum	19 mcg / 10 mL
Selenium	79 mcg / 10 mL
Zinc	5000 mcg / 10 mL

Multi-Trace Elements for Intravenous Nutrition

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TABLE OF CONTENTS

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

Addnutriv™, Trace Elements for Injection, is indicated as part of intravenous solutions for parenteral nutrition to meet basal to moderately increased requirements of the trace elements chromium, copper, iodide, iron, fluoride, manganese, molybdenum, selenium, and zinc in adults. It prevents depletion of endogenous stores of these elements and development of subsequent deficiency symptoms.

1.1 Pediatrics

Pediatrics:
No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

1.2 Geriatrics

Geriatrics (> 65 years of age): Evidence from clinical studies and experience suggests that Addnutriv can be used in geriatric population, see Warning section.

2 CONTRAINDICATIONS

Addnutriv, Trace Elements for Injection, is contraindicated in patients who are hypersensitive to this product or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see Dosage Forms, Strengths, Composition and Packaging.

Addnutriv is also contraindicated in:
- Conditions with total biliary obstruction.
- Wilson's disease, hemochromatosis.

3 DOSAGE AND ADMINISTRATION

3.1 Dosing Considerations

- In patients with renal or hepatic impairment or mild cholestasis, the dose should be adapted.
- In general, longer infusion periods are desirable, as this may minimize renal losses. The typical infusion time for parenteral nutrition is 8 hours.

3.2 Recommended Dose and Dosage Adjustment

Adults: The recommended daily dosage of Addnutriv, in adult patients with basal to moderately increased requirements, is 10 mL (one ampoule).

Pediatrics: Health Canada has not authorized an indication for pediatric use.

3.3 Administration

Addnutriv must not be given undiluted. Addnutriv should be diluted in a parenteral nutrition solution / emulsion before given as an intravenous infusion.

3.4 Reconstitution and Mixing Guidelines

Aseptic addition of Addnutriv, Trace Elements for Injection, to the amino acid or dextrose component of a parenteral nutrition solution under a laminar flow hood conditions is recommended. Addnutriv may only be added to medications and parenteral nutrition solutions for which compatibility has been shown.

Addnutriv is used as an additive to parenteral nutrition admixtures in compounded bags where data are available. Compatibility data are available for the addition of 10 mL Addnutriv to parenteral nutrition products (i.e. SmofKabiven®, Intralipid® 20% and SMOFlipid®), dextrose and electrolytes in prescribed concentrations.

Mixing Guidelines
Admixtures should be prepared in bags suitable for parenteral nutrition compounding according to a defined mixing sequence.

Addnutriv should never be added directly to a lipid emulsion because of the destabilizing effects of trace elements. When adding Addnutriv to SmofKabiven®, a three-chamber bag, it is recommended that the macronutrients from each chamber (amino acid solution, dextrose solution and lipid emulsion) are mixed first (bag activation), before adding Addnutriv and any other additives. Any other additions to the bag should be evaluated by a pharmacist for compatibility. Questions about compatibility may be directed to Fresenius Kabi Canada.

When compounding admixtures, from individual macronutrients and micronutrients, in empty suitable bags, the admixing sequence below may be followed:

1. Add Addnutriv and electrolytes (except phosphate solution) to the amino acid solution, mixing well between additions
2. Add phosphate to the dextrose solution
3. Add the above two solutions to the bag and mix well
4. Add vitamins to the lipid emulsion (SMOFlipid 20% or Intralipid 20%)
5. Add the mixture to the bag and mix well

4 OVERDOSAGE

In patients with impaired renal or biliary function, there is an increased risk of accumulation of trace elements.

In case of a chronic overload of iron there is a risk of hemosiderosis, which in severe and rare cases can be treated by phlebotomy.

For management of a suspected drug overdose, contact your regional poison control centre.

5 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1 – Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredients
Intravenous infusion	Trace Elements for Injection Each 10 mL ampoule contains: Chromic chloride hexahydrate 53.3 mcg Cupric chloride dihydrate 1.02 mg Ferric chloride hexahydrate 5.4 mg Manganese chloride tetrahydrate 198 mcg Potassium iodide 166 mcg Sodium fluoride 2.1 mg Sodium molybdate dihydrate 48.5 mcg Sodium selenite 173 mcg Zinc chloride 10.5 mg	Hydrochloric acid, water for injection, xylitol

The active ingredients of Addnutriv correspond to:

Element	Concentration in 10 mL	
	(mcg)	(mcmol)
Chromium (Cr^{3+})	10	0.2
Copper (Cu^{2+})	380	6
Iron (Fe^{3+})	1100	20
Manganese (Mn^{2+})	55	1
Iodine (I^{-})	130	1
Fluoride (F^{-})	950	50
Molybdenum (Mo^{6+})	19	0.2
Selenium (Se^{4+})	79	1
Zinc (Zn^{2+})	5000	77

The content of sodium and potassium in 10 mL corresponds to:

Sodium	1200 mcg	52 mcmol
Potassium	39 mcg	1 mcmol

Osmolality: approximately 3100 mosm/kg water
pH: 2.5

Packaging

Addnutriv, Trace Elements for Injection, is available in 10 mL polypropylene ampoules in cartons of 20 units.

6 WARNINGS AND PRECAUTIONS

General
Patients should be clinically observed for signs and symptoms of hypersensitivity reactions. In case of hypersensitivity reactions, the infusion should be stopped immediately, and appropriate measures should be taken.

Parenterally administered iron or iodine preparations can cause hypersensitivity reactions on rare occasions, including serious and potentially fatal anaphylactic reactions.

If iron is taken orally in parallel with the administration of Addnutriv, the total intake of iron should be determined to ensure that there is no iron accumulation.

If the treatment is continued for more than 4 weeks, checking of manganese levels in blood is required.

Hepatic/Biliary/Pancreatic
Addnutriv should be used with caution in patients with impaired biliary function in whom the excretion of trace elements may be significantly decreased.

Addnutriv should be used with caution in patients with biochemical or clinical evidence of liver dysfunction (especially cholestasis). Liver dysfunction, including impaired biliary excretion, may interfere with excretion of trace elements, leading to a risk of accumulation
.
Renal
Addnutriv should be used with caution in patients with impaired renal function in whom the excretion of trace elements may be significantly decreased.

6.1 Special Populations

6.1.1 Pregnant Women

Animal reproduction studies or clinical investigations during pregnancy have not been carried out with Addnutriv. The requirements of trace elements in a pregnant woman are slightly increased compared to non-pregnant women.

There is no sufficient data available on use of Addnutriv in pregnant women.

Healthcare professionals should carefully consider the potential risks and benefits for each pregnant patient before prescribing Addnutriv.

6.1.2 Breast-feeding

It is unknown to what extent Addnutriv is excreted in human milk. Because many drugs are excreted in human milk precaution should be exercised.

Healthcare professionals should carefully consider the potential risks and benefits for each case before prescribing the product.

6.1.3 Pediatrics

No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

6.1.4 Geriatrics

In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

7 ADVERSE REACTIONS

7.1 Adverse Reaction Overview

Adverse reaction information is based on post-marketing experiences.

7.2 Post-Market Adverse Reactions

Adverse drug reactions with trace elements, administered in combination with parenteral nutrition products, have been reported, and may have been caused by any component of the parenteral nutrition. They were reported at much lower frequencies (< 0.0000001) than the lowest "very rare" frequency of < 1 / 10 000.

Table 2: Serious ADRs by preferred term reported for trace elements

SOC	Preferred ADR term
Cardiac disorders	Cardiac arrest Arrhythmia Palpitations Tachycardia
Gastrointestinal disorders	Diarrhea Nausea Vomiting
General disorders and administration site conditions	Administration site reaction Chest pain Chest discomfort Chills Death Malaise (Hyper-) Pyrexia Infusion site phlebitis Injection site pain, Pain Swelling (Peripheral) swelling Asthenia
Hepatobiliary disorders	Hepatic function abnormal Jaundice Hepatic failure

SOC	Preferred ADR term
Immune system disorders	Hypersensitivity Anaphylactic shock
Infections and infestations	Abdominal sepsis Candida infection Vascular device infection Infective pulmonary exacerbation of cystic fibrosis Dysentery Infection Pneumonia Sepsis Urinary tract infection
Injury, poisoning and procedural complications	Hip fracture Product administration error Product dose omission Exposure during pregnancy Product prescribing error Medication error Product use in unapproved indication
Investigations	Blood pressure increased Body temperature increased General physical condition abnormal Liver function test abnormal Oxygen saturation decreased Blood potassium increased Renal function test abnormal Urine output decreased Hyperglycemia Hypernatraemia Hyponatraemia Refeeding syndrome Hypovitaminosis
Musculoskeletal and connective tissue disorders	Back pain Muscle spasms Myalgia Muscle twitching
Nervous system disorders	Cerebral infarction Dysgeusia Headache Paraesthesia Seizure Poor quality sleep Tremor Loss of consciousness
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous
Psychiatric disorders	Nervousness
Renal and urinary disorders	Renal impairment

SOC	Preferred ADR term
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema Dyspnea Respiratory failure
Skin and subcutaneous tissue disorders	Cold sweat Erythema Pruritus Rash Hyperhidrosis Urticaria
Vascular disorders	Embolism Flushing Hypotension Thrombophlebitis Thrombosis

8 DRUG INTERACTIONS

8.1 Drug-Drug Interactions

No drug interaction with trace elements have been reported, at the concentrations present in Addnutriv, other than the following:

- Molybdenum interacts with copper to form complexes that increase urinary elimination of copper;
- Amino acids, which are present in all total intravenous nutritional mixtures, could form complex with zinc and copper and the complex could be excreted in urine. However, amino acid loss in urine is usually small;
- Interactions of copper with ascorbic acid from vitamins supplementation of the parenteral nutrition mixture may occur.

8.2 Drug-Food Interactions

The product is administered intravenously; therefore, there is no interaction with food.

8.3 Drug-Herb Interactions

Interactions with herbal products have not been established.

8.4 Drug-Laboratory Test Interactions

Interactions of trace elements on laboratory tests are not known.

8.5 Drug-Lifestyle Interactionsst

Addnutriv has no influence on the ability to drive and use machines.

9 ACTION AND CLINICAL PHARMACOLOGY

9.1 Mechanism of Action

Trace elements are important micronutrients that function as cofactors for the activity of many enzymes and are involved in the metabolism of macronutrients (protein, lipids, dextrose). To the same extent as orally absorbed trace elements, intravenously administered trace elements have the ability to correct clinical deficiency, maintain trace element status, and ensure proper utilization of energy and amino acid substrates.

9.2 Pharmacodynamics

Addnutriv is a mixture of trace elements in amounts normally absorbed from the oral diet and should have no pharmacodynamic effect besides maintaining or replenishing the nutritional status.

9.3 Pharmacokinetics

Absorption:
Addnutriv is administered intravenously with bioavailability of 100%.

Distribution and Metabolism:
Individual trace elements will be taken up by tissue to different extent. The uptake depends on the requirements of the tissue to maintain or restore the concentration of each trace element.

Elimination:
Copper and manganese are normally excreted via the bile, whereas fluoride, iodine, selenium, zinc, and chromium (especially in patients receiving parenteral nutrition) are mainly excreted in urine via the kidneys.

The main route of molybdenum excretion is in urine, although small amounts are excreted via the bile.

Iron is eliminated in small amounts by sweating and desquamation of skin and gut cells. Premenopausal women can lose 30 to 150 mg of iron in the monthly blood loss.

10 STORAGE, STABILITY AND DISPOSAL

Shelf life of the product: 3 years.

Store at room temperature (15°C to 30°C). Do not freeze. No special precautions for storage of the unopened ampoule.

Do not use if the ampoule is damaged.

Addnutriv is for single use in one patient only. Any unused product should be discarded.

Storage after mixing

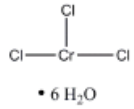
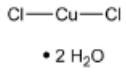
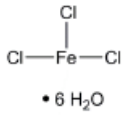
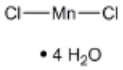
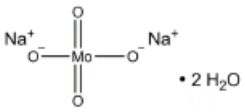
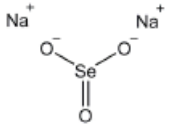
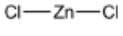
Chemical and physical in-use stability after dilution has been demonstrated for 24 hours at 25 °C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be

longer than 24 hours at 2 °C to 8 °C, unless mixing has taken place in controlled and validated aseptic conditions.
As with all parenteral drug products, reconstituted solution and intravenous admixtures should be inspected visually for clarity, particulate matter, precipitate, discoloration and leakage prior to administration, whenever solution and container permit. Solutions showing haziness, particulate matter, precipitate, discoloration or leakage should not be used. Discard unused portion.

PART II: SCIENTIFIC INFORMATION

11 PHARMACEUTICAL INFORMATION

Drug Substance

Chemical Name	Structural Formula	Molecular Formula and Molecular Mass	Physicochemical properties
Chromic chloride hexahydrate	$CrCl_3 \cdot 6\ H_2O$		• freely soluble in water, soluble in alcohol • pH: 2 - 3
Copper chloride dihydrate	$CuCl_2 \cdot 2\ H_2O$		• freely soluble in water, soluble in alcohol • pH: 3 – 3.8
Ferric chloride hexahydrate	$FeCl_3 \cdot 6\ H_2O$		• freely soluble in water, soluble in alcohol, ether, acetone • pH: 1.8
Manganese chloride tetrahydrate	$MnCl_2 \cdot 4\ H_2O$		• freely soluble in water, soluble in alcohol • pH: 5.5
Potassium iodide	KI		• very soluble in water, freely soluble in glycerol, soluble in ethanol (96 %)
Sodium fluoride	NaF		• soluble in water, practically insoluble in ethanol (96%)
Sodium molybdate dihydrate	$Na_2MoO_4 \cdot 2\ H_2O$		• freely soluble in water • pH: 9 - 10
Sodium selenite	Na_2SeO_3		• soluble in water • pH: 9
Zinc chloride	$ZnCl_2$		• freely soluble in water, soluble in alcohol, glycerol, ether, acetone • pH: 5

12 CLINICAL TRIALS

Study demographics and trials design

One prospective, uncontrolled, open-label study (Shenkin 4204) was conducted, in the post-operative period of surgical patients with gastrointestinal disease requiring parenteral nutrition, to evaluate efficacy and safety of Addamel N*, the reference product registered internationally. A total of 16 patients (age range 26 to 77 years; 6 females, 10 males) were administered intravenously 10 mL (1 vial) of Addamel N, daily as part of their parenteral nutrition regimen for at least seven days.

One prospective, uncontrolled, open-label study (Shenkin 4854) was conducted in post-operative surgical patients and patients with inflammatory bowel disease requiring parenteral nutrition to evaluate efficacy and tolerance of Addamel. A total of 28 patients (age range 18 to 81 years; 12 females and 16 males) were administered intravenously 10 mL (1 vial) Addamel daily as part of their parenteral nutrition regimen for at least seven days.

Table 3 - Summary of patient demographics studies with Addamel

Study No.	Trial design	Dosage	Route of administration	Duration	Treated subjects (n)	Age (years)
Shenkin 4854 Efficacy and tolerance	Prospective, uncontrolled, open-label	10 mL (1 vial)	IV as part of parenteral nutrition	≥7 days	28	≥18
Shenkin 4204 Efficacy and safety	Prospective, uncontrolled, open-label	10 mL (1 vial)	IV as part of parenteral nutrition	≥7 days	16	≥26

IV: intravenous; n: number

**Addnutriv is the third generation of multitrace elements; whereas Addamel N, is its predecessor and the reference product used for Addnutriv to establish its safety and efficacy.*

Study results

In study Shenkin 4204, biochemical assessment indicated that the level of trace element provision was adequate for most patients. No clinical signs of trace element deficiency or toxicity were observed during the study. Parenteral nutrition was well tolerated in most patients. The feeding regimen of two patients had to be stopped due to *Staphylococcus aureus* septicemia, and 2 other patients developed catheter sepsis after study completion. No adverse reactions occurred in this study that could be related to the use of Addamel N. Addamel N was safe and well-tolerated.

The biochemical assessment in Shenkin 4854 showed that levels of zinc and copper provision were adequate for most patients, the manganese and chromium provision was excessive, and the level of selenium provision was adequate for maintenance but inadequate to correct a pre-existing depletion. No clinical signs of trace element deficiency or toxicity were observed during the study. Three patients died during the study due to complications of underlying diseases. The other 21 patients survived, and the clinical progress was satisfactory in relation to diagnosis. No adverse reactions occurred in this study that could be related to the use of the product. Addamel was safe and well-tolerated.

The safety results of studies Shenkin 4854 and Shenkin 4204 as well as the absence of reported adverse events in numerous publications of studies with Addamel products in combination with the safety profile

from post-marketing surveillance with Addamel N and Addnutriv supports the safe use of Addnutriv, if used in the approved dose.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Addnutriv™
Trace Elements for Injection

Read this carefully before you start taking Addnutriv and each time you get an infusion. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Addnutriv.

What is Addnutriv used for?

- Addnutriv is used along with other products that contain nutrients that are given to you through an infusion into your vein.
- It contains trace elements which are nutrients that your body needs in very small amounts.
- It is given to meet your body's trace element needs when you cannot eat normally.
- It is used in adults only.
- It prevents reduction of trace elements in your body and feeling unwell due to their lack.

How does Addnutriv work?

Addnutriv gives you the trace elements that your body needs. These are given directly into your blood. The trace elements are then used by your body for many different functions.

What are the ingredients in Addnutriv?

Medicinal ingredients

Chromium	(as Chromic chloride hexahydrate)
Copper	(as Cupric chloride dihydrate)
Iron	(as Ferric chloride hexahydrate)
Manganese	(as Manganese chloride tetrahydrate)
Iodine	(as Potassium iodide)
Fluoride	(as Sodium fluoride)
Molybdenum	(as Sodium molybdate dihydrate)
Selenium	(as Sodium selenite)
Zinc	(as Zinc chloride)

Non-medicinal ingredients: hydrochloric acid water for injection and xylitol.

Addnutriv comes in the following dosage forms:

As a solution that contains:

Chromium	10 micrograms / 10 mL
Copper	380 micrograms / 10 mL
Iron	1100 micrograms / 10 mL
Manganese	55 micrograms / 10 mL
Iodine	130 micrograms / 10 mL
Fluoride	950 micrograms / 10 mL
Molybdenum	19 micrograms / 10 mL
Selenium	79 micrograms / 10 mL
Zinc	5000 micrograms / 10 mL

Do not use Addnutriv if you:

- are allergic to Addnutriv.
- are allergic to any of the ingredients in Addnutriv or to a component of the container.
- have a biliary obstruction, a condition where your bile ducts are blocked.
- have Wilson's disease, a genetic disorder where your body stores too much copper.
- have hemochromatosis, a condition where your body stores too much iron.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive Addnutriv. Talk about any health conditions or problems you may have, including if you:

- have kidney problems.
- have liver problems.
- have a condition called cholestasis where bile does not flow properly from the liver to the intestine.
- are taking an iron supplement by mouth in addition to Addnutriv. Your doctor will make sure that too much iron does not collect in your body.
- are pregnant.
- are breast-feeding.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or other medicines.

The following may interact with Addnutriv:

- Nutritional supplements that contain molybdenum.
- Vitamin C supplement that is given to you through an infusion into your vein

How to take Addnutriv:

- Addnutriv will be given to you by a healthcare professional.
- Your healthcare professional will make sure that Addnutriv is prepared correctly before it is given to you.
- It will first be mixed with another solution before it is given to you.
- It will then be infused slowly into your vein.
- It will usually be infused over a period of 8 hours.
- Follow all instructions given to you by your health care professional.

Usual dose:

- Your doctor will decide how much Addnutriv you will receive.
- The usual dose is 10 mL of Addnutriv a day.
- Your doctor may give you a lower dose of Addnutriv if you have:
  - kidney problems
  - liver problems
  - or if you have a condition called cholestasis where bile does not flow properly from the liver to the intestine

Overdose:

If you think you have taken too much Addnutriv, contact your healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using Addnutriv?

These are not all the possible side effects that you may feel when taking Addnutriv. If you experience any side effects not listed here, contact your healthcare professional.

Addnutriv is used along with other products that contain nutrients. **Serious side effects may include:**

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Very Rare			
Allergic Reaction: difficulty breathing, difficulty swallowing, fever, hives, itchy skin, loss of consciousness, rash, swelling of your tongue, throat or face.			✓
Digestive system problems: diarrhea, nausea, vomiting.		✓	
General: chills, pain, chest discomfort and pain, tiredness	✓		
Heart problems: heart beating too hard or too fast, skipping a beat, or fluttering, irregular heartbeats.		✓	
Infections: body aches and pains, chills, burning or pain with urination, coughing, fatigue, fever, new onset of pain, not feeling well, any unusual discharge from your body		✓	
Injection site reactions: pain, redness or swelling at the injection site.		✓	
Kidney problems: back and abdominal pain, change in the colour of urine (pale or dark), decrease in amount of urine produced, pain or discomfort when urinating, swelling of the legs and ankles.	✓		
Liver problems: abdominal pain, dark urine, fatigue, loss of appetite, nausea, swollen abdomen, vomiting, weakness, yellowing of the skin or eyes (jaundice).		✓	
Muscle problems: back pain, muscle cramps, pain or twitching	✓		
Lung problems: blue tint to the face and lips, shortness of breath, too much fluid in lung.	✓		
Skin problems: cold sweat, redness, sweating.	✓		
Blood clot in a vein: pain, tenderness, redness, warmth or swelling of a body area, swelling or hardening of a vein near the surface of the skin.		✓	
Low blood pressure		✓	

Addnutriv can cause abnormal blood test results. Your doctor may perform blood tests and will interpret the results. If you receive Addnutriv for more than 4 weeks, your doctor will check the levels of

manganese in your blood

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store at room temperature (15°C to 30°C). Do not freeze. No special precautions for storage of the unopened plastic container.

Keep out of reach and sight of children.

If you want more information about Addnutriv:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://health-products.canada.ca/dpd-bdpp/index-eng.jsp); the manufacturer's website (https://www.fresenius-kabi.com/en-ca/), or by calling 1-877-821-7724.

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