PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

MICRO +4 REGULAR STRENGTH

4 Trace Elements Injection

Zinc, 1 mg/mL
Copper, 0.4 mg/mL
Manganese, 0.1 mg/mL
Chromium, 4 mcg/mL
USP
Intravenous

Combination of Electrolytes

Sandoz Canada Inc.
110 Rue de Lauzon
Boucherville, Québec, Canada
J4B 1E6

Date of Preparation:
APR 25, 1994

Date of Revision:
MAY 03, 2024

Control No.: 278926

RECENT MAJOR LABEL CHANGES

4 DOSAGE AND ADMINISTRATION, 4.2 Recommended Dose and Dosage Adjustment (Pediatrics)	05/2021
7 WARNINGS AND PRECAUTIONS, General	05/2021

TABLE OF CONTENTS

Sections and Subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

MICRO +4 REGULAR STRENGTH (4 Trace Elements Injection USP) is indicated for:

- use as a supplement to intravenous solutions given for TPN. Its administration in TPN solutions helps to maintain plasma zinc, copper, manganese and chromium levels and to prevent depletion of endogenous stores of these elements and development of subsequent deficiency symptoms.

1.1 Pediatrics (≤ 18 years of age): MICRO +4 REGULAR STRENGTH is indicated for use in pediatric patients (see 4.2 Recommended Dose and Dose Adjustments).

1.2 Geriatrics (≥ 65 years of age): MICRO +4 REGULAR STRENGTH is indicated for use in geriatric patients. No dosage adjustments are required.

2 CONTRAINDICATIONS

- MICRO +4 REGULAR STRENGTH is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

Routine monitoring of zinc, copper, manganese, and chromium plasma levels is suggested as a guideline for administration.

Zinc

Normal plasma levels vary from approximately 68 to 136 mcg per 100 mL. Frequently monitor the blood zinc levels for those patients receiving more than the usual maintenance dosage level of zinc.

Copper

While the normal adult plasma levels range from 90 to 130 mcg/100 mL, the normal full-term newborn's serum levels are about one-third of this. These values were found to rise gradually during the first week of life, fall to below adult levels at two months of age, rise to within the adult range at three months of age, and to rise still higher above the adult range at eight months of age, at which levels the values persisted throughout the remainder of infancy.

Manganese

Manganese is bound in both the serum and the erythrocytes. Normal human blood values have been recognized as 6 to 10 mcg/mL.

Chromium

Changes in serum chromium following glucose loading or insulin injection should be regarded with caution as indicators of chromium status. Serum levels of 1 to 31 ng/mL have been

reported. Levels of chromium in hair may provide a more useful index of chromium status, with 900 ppb in newborn infants, 440 ppb in children 24-36 months of age, and 0.75 mcg chromium/g of hair in nulliparous women reported.

4.2 Recommended Dose and Dosage Adjustment

The suggested dosage ranges for the four trace elements are:

Zinc
Adults
For the metabolically stable adult receiving TPN, the suggested intravenous dosage level is 2.5 to 4 mg of zinc per day.

For acute catabolic states an additional 2 mg of zinc per day is suggested.

For the stable adult with fluid loss from the small bowel, an additional 12.2 mg of zinc per litre of TPN solution; or an additional 17.1 mg of zinc per kg of stool or ileostomy output is recommended.

Pediatrics (≤ 18 years of age)
For full-term infants and children up to 5 years of age, 100 mcg zinc/kg/day is recommended.

For premature infants weighing up to 3 kg in body weight, 300 mcg zinc/kg/day is recommended.

Copper
Adults
For the metabolically stable adult receiving TPN, the suggested additive dosage level is 0.5 to 1.5 mg copper per day.

Pediatrics (≤ 18 years of age)
For pediatric patients the suggested dosage level is 20 mcg copper per kg daily.

Manganese
Adults
For the metabolically stable adult receiving TPN, 0.15 to 0.8 mg/day is suggested as the additive dosage level for manganese.

Pediatrics (≤ 18 years of age)
The following dosage levels of manganese are recommended:

Infants up to 10 kg:	≤ 1 mcg per kg/day
Children ≤ 15 kg:	1 mcg per kg/day, with a maximum daily dose of 15 mcg
Children 15.1 to 40 kg:	15 mcg per kg/day
Children and adolescents > 40 kg:	the adult preparations of trace elements should be prescribed.

See 7 WARNINGS AND PRECAUTIONS.

Chromium
Adults

For the metabolically stable adult receiving TPN, 10 to 15 mcg of chromium per day is suggested as the additive dosage level.

The metabolically stable adult with intestinal fluid loss may require 20 mcg of chromium daily with frequent monitoring of blood levels as a guideline for subsequent administration.

Pediatrics (≤ 18 years of age)
For pediatric patients, 0.14 to 0.20 mcg/kg/day is suggested as the additive dosage level.

4.3 Reconstitution
Not applicable

4.4 Administration

Dilution for Intravenous Use:
Aseptic addition of MICRO +4 REGULAR STRENGTH to the amino acid/dextrose component of a TPN solution under a laminar flow hood is recommended. After dilution, the solution must be used within 24 hours, see 11 STORAGE, SATBILITY AND DISPOSAL.

Visually inspect parenteral drug products for particulate matter and discolouration prior to administration whenever container and solution permit.

5 OVERDOSAGE

Zinc
Zinc toxicity can occur by oral administration, inhalation and hemodialysis. Ingestion of excess zinc has usually resulted from storage of food or beverages in galvanized containers which results in diarrhea, vomiting and fever. One report of intoxication following inhalation of zinc oxide fumes causing fever, headache and vomiting has been reported in the literature. In 1972, a case of zinc poisoning was reported in a patient on hemodialysis with zinc-contaminated water. The patient developed nausea, vomiting, fever and severe anemia.

Infusions of 40 to 80 mg/day of zinc have been used with no apparent ill effects. No adverse effects were reported when a group of 22 patients received a 20 mg infusion before and after surgery. One case of ill effects was reported when a daily 10 mg dose of zinc was infused over one hour for 5 days. The ill effects were tachycardia, hypothermia, profuse sweating and blurred vision.

One death resulted from an overdose of intravenous zinc which was due to a local prescribing error. A 72 year old woman with a high output enterocutaneous fistula inadvertently received a 44 mmol(7.4 g) of zinc sulfate infused over a 60-hour period. Analysis of her serum zinc showed a zinc level of 4184 mcg/100 mL. Clinical manifestations were edema, jaundice, vomiting, diarrhea and oliguria.

Seven patients who received an accidental overdosage (25 mg zinc/litre TPN solution; equivalent to 50 to 70 mg zinc/day) exhibited hyperamylasemia (557 to 1850 Klein Units; normal 130 to 310).

Copper

Ingestion of excess copper due to the storage of food or beverages in copper or brass vessels, and beverage vending machines has resulted in acute gastrointestinal illness. Adverse reactions experienced following the ingestion of large doses of copper sulfate (1 to 50 g) include nausea, vomiting, metallic taste, burning sensation in the œsophagus and stomach, colic, bloody diarrhea, convulsions, hypotension and coma, renal damage with acute kidney necrosis, jaundice associated with liver injury and hæmolysis, anuria/oliguria, and hemolytic anemia.

Symptoms of copper toxicity that have been reported include prostration, behavior change, diarrhea, progressive marasmus, hypotonia, photophobia and peripheral edema.
D- penicillamine has been reported effective as an antidote.

Manganese
Manganese toxicity (manganism), a rare central nervous system disease, can occur following chronic occupational exposure to the dust from manganese ore fumes in steel processing. A metal fume fever syndrome can occur after exposure to high concentrations of manganese oxide; a few cases of pneumonitis have been associated with manganese exposure.

High doses of manganese can lead to deposition in the basal ganglia of the brain and cause toxic events that manifest symptomatically as Parkinson-like signs and symptoms, in addition to neuropsychiatric symptoms. If treatment lasts more than 4 weeks, manganese levels must be checked and if there is an excess of manganese, the administration of the parenteral nutrition should be stopped and corrective measures should be initiated.

Chromium
Trivalent chromium has been administered to TPN patients exhibiting chromium deficiency at dosage levels up to 250 mcg/day for two weeks with no signs of chromium toxicity.

Symptoms of chromium toxicity that have been reported for other compounds include nausea, vomiting, anemia, gastroenteritis and renal and hepatic damage.

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

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table – Dosage Forms, Strengths, Composition and Packaging.

Route of Administration	Dosage Form/ Strength	Non-medicinal Ingredients
Intravenous	Liquid / zinc: 1 mg/ mL copper: 0.4 mg/ mL manganese: 0.1 mg/ mL chromium: 4 mcg/ mL	Nitric acid, water for injection.

MICRO +4 REGULAR STRENGTH (4 Trace Elements Injection USP) is a sterile multi-element additive of 4 trace elements for use as an additive for Total Parenteral Nutrition (TPM). Each mL of Micro +4 Injection contains 1 mg/mL of zinc as zinc sulfate heptahydrate, 0.4 mg/mL copper as cupric sulfate penthydrate, 0.1 mg/mL manganese as manganese sulfate monohydrate and 4 mcg/mL chromium as chromium chloride hexahydrate.

MICRO +4 REGULAR STRENGTH (4 Trace Elements Injection USP) is supplied as 5 mL preservative free single use amber vials, boxes of 10.

The stopper is not made with natural rubber latex.

7 WARNINGS AND PRECAUTIONS

General
MICRO +4 REGULAR STRENGTH (4 Trace Elements Injection USP) is a hypotonic solution which should be administered in admixtures only.

If toxicity symptoms occur due to any one of the trace elements in MICRO +4 REGULAR STRENGTH, discontinue supplementation of TPN solutions immediately.

Do not give undiluted MICRO +4 REGULAR STRENGTH by direct injection into a peripheral vein because of the potential of infusion phlebitis.

Endocrine and Metabolism
In diabetic patients, the contribution of chromium supplementation for maintenance of normal glucose homeostasis has to be taken into account. In all diabetic patients, the hyperglycemia should also be controlled with appropriate therapy.

Hepatic / Biliary / Pancreatic
The possibility of copper and manganese retention should be a consideration in patients with biliary obstruction and caution should be exercised since copper and manganese are eliminated *via* the bile.

Neurologic
Excess of manganese can lead to deposition in the basal ganglia of the brain and cause toxic events that manifest symptomatically as Parkinson-like signs and symptoms, in addition to neuropsychiatric symptoms.

Renal
The possibility of zinc retention should be a consideration in patients with renal dysfunction and caution should be exercised since zinc is excreted *via* the kidneys.

7.1 Special Populations

7.1.1 Pregnant Women
It is not known whether MICRO +4 REGULAR STRENGTH can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity.

7.1.2 Breast-feeding
It is unknown if MICRO +4 REGULAR STRENGTH is excreted in human milk. Precaution should be exercised because many drugs can be excreted in human milk.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

No adverse reactions have been reported for the amount of zinc, copper, manganese, or chromium present in this product. The amounts are small and toxicity symptoms are not likely to occur at the suggested dosage level.

9 DRUG INTERACTIONS

9.2 Drug Interactions Overview
No drug interactions have been established.

9.4 Drug-Drug Interactions
Interactions with drugs have not been established.

9.5 Drug-Food Interactions
Interactions with food have not been established.

9.6 Drug-Herb Interactions
Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions
Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action
Zinc
Zinc is an essential nutritional element that is important in many enzyme systems either as a metalloenzyme or as an enzyme activator. More than 70 different zinc metalloenzymes have been characterized including carbonic anhydrase, alkaline phosphatase, alcohol dehydrogenase, procarboxypeptidase, superoxide dismutase, glyceraldehyde-3-P dehydrogenase and retinene reductase.

A zinc metalloenzyme is also involved in the synthesis of RNA and DNA, making it important in the normal growth and development process. Zinc facilitates wound healing and helps maintain the senses of taste and smell and normal skin hydration.

Copper
Copper is an essential nutritional element that is important in many enzyme systems either as a metalloenzyme or an enzyme activator such as: cytochrome-c-oxidase, dopamine-β-hydroxylase, monamine oxidase, superoxide dismutase, tyrosinase, urate oxidase, ceruloplasmin, ferroxidases and metallothionine.

The clinical importance of copper is related to the development and maintenance of collagen protein cross-linkage, structure and function of the central nervous system, iron metabolism, erythropoiesis and pigmentation.

Manganese
Manganese, an essential nutrient, is a component of several metalloenzymes, pyruvate carboxylase and superoxide dismutase, and a cofactor of a large number of enzyme systems including polymerase, galactotransferase, arginase and cholinesterase.

Manganese deficiency has been demonstrated in numerous animals and in one human subject with vitamin K deficiency whose symptoms included a delayed blood clotting response, mild evanescent dermatitis, reddening of hair and beard, slowed growth of hair, nails and beard, occasional nausea and vomiting, coincident decrease of serum phospholipids and triglycerides, and moderate weight loss.

Chromium
Trivalent chromium, an essential element, is a component of glucose tolerance factor which facilitates the reaction of insulin with receptor sites of insulin-sensitive tissues. Chromium helps to maintain normal glucose metabolism and peripheral nerve function.

Administration of chromium supplements to chromium deficient patients can result in normalization of the glucose tolerance curve from the diabetic-like curve typical of chromium deficiency. This response is viewed as a more meaningful indicator of chromium levels.

When chromium was administered intravenously to diabetics, increased chromium urinary levels were observed as compared to normal persons.

10.2 Pharmacodynamics
Zinc
In a study with 99 healthy young men, a mean serum zinc concentration of 102 mcg/100 mL (range 68-136) was reported. Thirty to forty percent of plasma zinc is bound to alpha 2-macroglobulin and sixty to seventy percent is loosely bound to albumin.

Profound changes in zinc blood levels are seen in various disease states and under stress conditions. Subnormal plasma zinc levels have been reported in patients with malignant tumours, atherosclerosis, postalcoholic cirrhosis of the liver and other liver diseases, tuberculosis and after acute tissue injury, regardless of origin.

Zinc deficiency occurs during long term TPN and, in some cases, during short term TPN, particularly in patients with long-standing enteropathies. TPN patients with zinc deficiency are characteristically apathetic, depressed, and develop diarrhea, alopecia, and a moist eczematous rash in the nasolabial fold, followed by bullous or pustular lesions on other parts of the face, in the groin, and on the hands and feet. These conditions are reversed or relieved by zinc administration. All or some of these zinc deficiency symptoms have been reported in adults, children and premature infants, the most predominant clinical manifestations reported being skin lesions and diarrhea resembling symptoms of acrodermatitis enteropathica.

Plasma zinc levels also declined in premature infants maintained on TPN without supplementation. During the last 10 to 12 weeks of pregnancy, two-thirds of the infant’s zinc stores are transferred from the mother. This patient population is at high risk of developing zinc deficiency because they are born with low body stores, need zinc for growth and may be in negative zinc balance up to 60 days after birth.

Therefore, providing zinc during TPN prevents development of the following deficiency symptoms: parakeratosis, hypogeusia, anorexia, dysosmia, geophagia, hypogonadism, growth retardation and hepatosplenomegaly.

Copper

Copper deficiency has been recognized in infants on cow's milk diets and in malnourished infants being rehabilitated on high-calorie low copper diets. Symptoms experienced include anemia, hypoproteinemia, low serum copper and iron levels, neutropenia, diarrhea and "scurvy-like" bone changes.

Adults and children receiving total parenteral nutrition without copper supplementation have shown these samesymptoms along with a parallel decline in plasma copper.

Copper supplementation during TPN helps prevent development of the following deficiency symptoms: leukopenia, neutropenia, anemia, depressed ceruloplasmin levels, impaired transferrin formation and secondary iron deficiency.

Manganese
Administration of manganese helps prevent deficiency symptoms such as nausea and vomiting, weight loss, reduced phospholipid and triglyceride plasma levels, dermatitis and changes in growth and colour of hair.

Chromium
Chromium supplementation during TPN helps prevent deficiency symptoms which include impaired glucose tolerance, ataxia, peripheral neuropathy and a confusional state similar to mild/moderate hepatic encephalopathy.

10.3 Pharmacokinetics
Absorption:
Zinc
Zinc is absorbed primarily from the small intestine.

Copper
Copper is absorbed primarily from the stomach and jejunum; however the exact mechanism of absorption is not clear.

Manganese
Dietary manganese is poorly absorbed.

Distribution:
Zinc
The distribution of zinc is wide and nonuniform with the highest concentrations found in the eye, prostate, kidney, liver, muscle, bones, teeth (dental enamel), hair, nails and skin. Zinc is also present in the blood with 75-88% of the total zinc of normal human blood in the red cells, 12-22% in the plasma and 3% in the leukocytes. Normal zinc levels are 8.8 mcg/mL in whole blood, 1.21 mcg/mL in plasma, and 14.4 mcg/mL in erythrocytes.

Copper
In man, the highest concentrations of copper are found in the liver and brain. Normal serum plasma levels range from 90 to 130 mcg/100 mL (mean, approximately 110 mcg/100 mL).

Manganese
It is estimated that the body of a normal 70 kg man contains 12 to 20 mg of manganese. This relatively small amount is widely distributed without notable concentration. However manganese concentration tends to be higher in tissues rich in mitochondria (liver, kidney and pancreas). Reserve manganese stores do not normally occur.

Chromium
The distribution of chromium occurs throughout the body in low concentrations without special concentration in any one tissue. Plasma chromium is bound to siderophilin (transferrin) a β1 globulin. Serum levels of 1 to 31 ng chromium per mL have been reported. Tissue uptake is rapid with plasma clearance occuring in several days. Since there does not appear to be an equilibrium between plasma and tissue chromium, blood levels are not considered to accurately indicate body chromium status.

Metabolism:
Copper
Absorbed copper is loosely bound to serum albumin and amino acids for transport and exchange with tissues. After reaching the liver, copper is either stored or released for incorporation into erythrocuprein, ceruloplasmin and the numerous copper containing enzymes.

About 60% of the copper in red blood cells is associated with erythrocuprein while the remainder is more loosely bound to protein.

Copper in plasma is present in two main forms of which 90% is firmly bound to ceruloplasmin and a small percentage is loosely bound to albumin. The remainder is bound to amino acids and enzymes.

Age, diet, hormones and pregnancy influence liver and plasma concentrations of copper.

Manganese
Plasma manganese is bound to a β1 globulin, transferrin. Normal whole blood levels of manganese range from 6 to 10 mcg/L.

Elimination:
Zinc
The main route of zinc excretion is in the feces, which contains the total endogenously excreted zinc (pancreatic and intestinal secretions) and zinc not absorbed from the diet. Small amounts of zinc are lost in urine (0.3 to 0.6 mg/day). However, accumulative zincuria has been observed following major operations, severe burns, nephrosis, postalcoholic hepatic cirrhosis, hepatic porphyria and starvation. Zinc is also lost through sweat, in hair and sloughing skin.

In patients with gastrointestinal disease receiving total parenteral nutrition (TPN), abnormal zinc excretion occurred from the gastrointestinal tract in diarrheal stools and intestinal fluid lost through suction and fistulous discharge.

Copper
Copper is excreted primarily *via* the bile (approximately 80%) in the form of a nonabsorbable protein complex with a further 18% *via* the intestinal wall and 2-3% *via* urine. Consequently, ingestion of 2-5 mg of copper per day, would result in copper losses of 0.6 to 2 mg per day, with 0.01 to 0.06 mg in urine. Comparatively small amounts are lost through menstruation and in sweat.

Manganese

Bile is the major route of manganese excretion with the liver apparently maintaining manganese homeostasis. However, when the biliary route is blocked or overloaded, auxiliary routes, pancreatic juices and the walls of duodenum, jejunum and ileum, increase. Urinary excretion, which is negligible, can be increased by the administration of chelating agents.

Chromium

Chromium is excreted mainly in the urine (5-10 mcg/day) with small amounts lost in the feces *via* the bile and small intestine. In subjects not receiving total parenteral nutrition urinary chromium has been reported to be less than 5 mcg/day, whereas, patients receiving TPN excreted much higher levels ranging from 10 to more than 100 mcg chromium/day. A chromium balance in TPN patients can be assessed by the measurement of chromium input and output.

11 STORAGE, STABILITY AND DISPOSAL

Store between 15 and 30ºC. Protect from light. Protect from freezing.

12 SPECIAL HANDLING INSTRUCTIONS

Not applicable

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Zinc

Proper name:	Zinc sulfate
Chemical name:	Zinc sulfate heptahydrate
Molecular formula and Molecular mass:	$ZnSO_4 \cdot 7H_2O$, 287.5 g/mol
Physicochemical properties:	Zinc sulfate is an odourless, colourless, transparent, effloresce nt crystal or white crystalline powder with an astringent metallic taste and freely soluble in water.

Copper

Proper name:	Copper sulfate
Chemical name:	Copper sulfate pentahydrate
Molecular formula and molecular mass:	$CuSO_4 \cdot 5H_2O$, 249.68 g/mol
Physicochemical properties:	Copper sulfate occurs as a blue crystal powder. It effloresces slowly in dry air. Its solution is acid to litmus. It is freely soluble in water and in glycerin, very soluble in boiling water and slightly soluble in alcohol.

Manganese

Proper name:	Manganese sulfate
Chemical name:	Manganese sulfate monohydrate
Molecular formula and molecular mass:	$MnSO_4 \cdot H_2O$, 169.01 g/mol
Physicochemical properties:	Manganese sulfate is a pale red, slightly efflorescent crystal or purple odourless powder. It is soluble in water and insoluble in alcohol.

Chromium

Proper name:	Chromic chloride

Chemical name:	Chromic (III) chloride hexahydrate
Molecular formula and molecular mass:	$CrCl_3 \cdot 6H_2O$, 266.5 g/mol
Physicochemical properties:	Chromic chloride is a dark green, odourless, slightly deliquescent crystal. It is soluble in water and in alcohol, slightly soluble in acetone, and practically insoluble in ether.

14 CLINICAL TRIALS

This information was not available at the time of authorization.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

This information was not available at the time of authorization.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
MICRO +4 REGULAR STRENGTH
4 Trace Elements Injection USP

Read this carefully before you start taking **MICRO +4 REGULAR STRENGTH** and each time you get a refill. 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 **MICRO +4 REGULAR STRENGTH.**

What is MICRO +4 REGULAR STRENGTH used for?
MICRO +4 REGULAR STRENGTH is used with other nutrition products that are given to you through an infusion into your vein. It is given to you when you cannot eat normally. It helps maintain normal levels of nutrients (zinc, copper, manganese and chromium).

How does MICRO +4 REGULAR STRENGTH work?
Zinc, copper, manganese and chromium are essential nutrients for your body. MICRO +4 REGULAR STRENGTH works by maintaining normal levels of these nutrients in your blood. This helps prevent problems when levels of these nutrients are low.

What are the ingredients in MICRO +4 REGULAR STRENGTH?
Medicinal ingredients: zinc (as zinc sulfate heptahydrate), copper (as cupric sulfate pentahydrate), manganese (as manganese sulfate monohydrate), chromium (as chromic chloride hexahydrate).

Non-medicinal ingredients: nitric acid, water for injection.

MICRO +4 REGULAR STRENGTH comes in the following dosage form: liquid (1 mg zinc / mL, 0.4 mg copper / mL, 0.1 mg manganese / mL, 4 mcg chromium / mL).

Do not use MICRO +4 REGULAR STRENGTH if you:
- are allergic to zinc, copper, manganese, chromium or to any of the other ingredients of MICRO +4 REGULAR STRENGTH or to a component of the container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MICRO +4 REGULAR STRENGTH. **Talk about any health conditions or problems you may have, including if you:**
- have a liver condition where there is a blockage of the bile duct.
- have kidney disease.
- have diabetes.
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if MICRO +4 REGULAR STRENGTH passes into breastmilk.

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

There are no known relevant interactions at this time.

How to take MICRO +4 REGULAR STRENGTH:
- MICRO +4 REGULAR STRENGTH will be given to you into your vein by a healthcare professional.

- Your healthcare professional will make sure that MICRO +4 REGULAR STRENGTH is prepared correctly before it is given to you.
- Your healthcare professional will routinely monitor the nutrient levels in your blood.

Usual dose:
Your healthcare professional will decide on the actual dose of MICRO +4 REGULAR STRENGTH that is right for you based on your age, body weight and medical condition.

Overdose:

If you think you, or a person you are caring for, have taken too much **MICRO +4 REGULAR STRENGTH**, 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 MICRO +4 REGULAR STRENGTH?
There are no known side effects at this time. If you experience any side effects, tell 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:
Your healthcare professional will store MICRO +4 REGULAR STRENGHT at 15 - 30°C. Protect from light. Protect from freezing.
Keep out of sight and reach of children.

If you want more information about MICRO +4 REGULAR STRENGTH:
- 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 www.sandoz.ca or by calling 1-800-361-3062.

This leaflet was prepared by Sandoz Canada Inc.

Revised on MAY 03, 2024