PRODUCT MONOGRAPH

MICRO Se

Selenious Acid Injection USP

Trace Element

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Selenious Acid Injection USP

(40 µg/mL)

Trace Element

CLINICAL PHARMACOLOGY

Selenium is an essential component of glutathione peroxidase, an enzyme which helps prevent oxidative damage to cells caused by peroxides and free radicals.

The absorption, retention and distribution of selenium within the body, and the amounts, forms and routes of excretion vary with the chemical forms and amounts of the element ingested and with the dietary levels of other elements such as arsenic and mercury.

Selenium is absorbed from the small intestine and distributed widely to tissues including liver, skin, muscle, kidney, lung, brain, testis, ovary, heart, spleen, thyroid, pancreas, dental enamel and fingernails.

Blood levels have been shown to vary geographically due to selenium levels of soil and food. Reported values of selenium levels in whole blood vary from 150 ng/ml in selenium deficient areas to 3200 ng/ml in a seleniferous zone (in China). Studies in North America have reported

whole blood levels of 70 to 229 ng/ml and plasma levels of 78 to 157 ng/ml.

Excretion occurs mainly via the kidneys. However a small amount of the endogenous stores is lost through the feces.

Keshan disease, a cardiomyopathy of children and young women in China, is the only clinical condition that has been firmly linked to selenium deficiency. Plasma selenium levels have been shown to decrease during total parenteral nutrition (TPN), however symptoms of selenium deficiency are not seen in all TPN patients. Several factors may influence the development of selenium deficiency including geographical location, nutritional and clinical status, excessive GI losses, age, volume of fluid administered and duration of selenium-deficient TPN.

Several cases of cardiomyopathy have occurred in patients receiving total parenteral nutrition. Muscle pain and weakness have been reported during total parenteral nutrition and have responded to selenium supplementation.

Selenium supplementation during TPN helps prevent development of the following deficiency symptoms: cardiomyopathy, muscle pain and weakness.

INDICATIONS

MICRO Se (Selenious Acid Injection USP) is indicated as a supplement to intravenous solutions given for TPN. Its administration in TPN solutions helps to maintain plasma selenium levels, and to prevent depletion of endogenous stores of selenium and subsequent deficiency symptoms.

WARNINGS

MICRO Se is a hypotonic solution which should be administered in admixtures only.

If toxicity symptoms occur due to selenium, discontinue supplementation of TPN solutions immediately.

Do not give undiluted **MICRO Se** by direct injection into a peripheral vein because of the potential of infusion phlebitis.

PRECAUTIONS

The possibility of selenium retention should be considered in patients with renal dysfunction and/or gastrointestinal malfunction since selenium is eliminated in the urine and to a smaller extent in the feces.

ADVERSE REACTIONS

The amount of selenium present in **MICRO Se** is small. Symptoms of toxicity from selenium are unlikely to occur at the recommended dosage level.

OVERDOSAGE

Chronic selenium toxicity due either to occupation-related exposure, high selenium content in food/water or oral supplements, resembles arsenic toxicity. Hair loss, white horizontal streaking on fingernails, paronychia, fatigue, irritability, hyperreflexia, nausea, vomiting, garlic odor on breath, and metallic taste characterize toxicity. Muscle tenderness, tremor, lightheadedness, and facial flushing are observed in selenite poisoning. Serum selenium levels are elevated but do not correlate well with symptoms. Blood chemistries, hematology, and liver and renal function tests are usually normal.

Acute selenious acid ingestions are almost invariably fatal. Stupor, respiratory depression, hypotension, and death can result several hours postingestion. Severe hypotension develops secondary both to decreased contractility from a toxic cardiomyopathy and to inappropriately low peripheral vascular resistance. Laboratory abnormalities include thrombocytopenia, moderate hepatorenal dysfunction, and elevated serum creatine kinase levels.

The electrocardiogram may demonstrate ST elevations and T-wave changes characteristic of myocardial infarction. The urinary excretion of selenium is rapid. Terminal respiratory failure developed after a selenious acid ingestion (15 mL gun bluing solution) despite the use of an extracorporeal membrane oxygenator. Death occurred on the 18th hospital day. The plasma

selenium level reached 285µg/mL on the first hospital day and returned to normal levels by day 4.

There are no antidotes to selenious acid toxicity; treatment is expectant (cardiopulmonary monitoring in an intensive care setting) and supportive (intravenous infusion, supplemental oxygen and ventilation as needed).

DOSAGE AND ADMINISTRATION

Dosage:

The suggested dosage ranges are:

Adults

For the metabolically stable adult receiving TPN, the suggested additive dosage level is 20 to 40 µg selenium per day.

Pediatrics

For pediatric patients the suggested dosage level is 3 µg selenium per kg per day.

Administration:

Routine monitoring of selenium levels is suggested as a guideline for administration. The range for selenium blood levels has been reported as plasma, 78 to 157 ng/ml; whole blood, 70 to 229 ng/ml.

MICRO Se should be aseptically added to the TPN solution under the laminar flow hood. The selenious acid present in MICRO Se is physically compatible with electrolytes and vitamins usually present in the amino acid/dextrose solution used for TPN.

PHARMACEUTICAL INFORMATION

DRUG SUBSTANCE

Proper Name: Selenious Acid

Chemical Name: Selenium di-oxide, monohydrated

Molecular Formula: H_2SeO_3

Molecular Weight: 128.97

Description: Selenious Acid is a colourless or white crystal, efforescent in dry air and hygroscopic in moist air. It is insoluble in water and in alcohol.

COMPOSITION

Each mL of **MICRO Se** contains 65.36 µg of Selenious acid (equivalent to 40 µg Selenium). Nitric acid is used to adjust the pH.

DILUTION FOR INTRAVENOUS USE

Aseptic addition of **MICRO Se** 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. Visually inspect parenteral drug products for particulate matter and discolouration prior to administration whenever container and solution permit.

STABILITY AND STORAGE RECOMMENDATIONS

Store between 15 and 28ºC. Do not permit to freeze.

The chlorobutyl rubber stopper is not made with natural rubber latex

AVAILABILITY

One strength, 40 µg selenium/mL, is available in single dose 10 mL clear glass vials in boxes of 10.

MICRO Se is for intravenous use after dilution only.

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