PRODUCT MONOGRAPH

# MICRO Cr

**Chromic Chloride Injection USP**

($Cr^{3+}$ 4 mcg/mL)

Trace Element

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## CLINICAL PHARMACOLOGY

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.

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 $\beta_1$ globulin. Serum levels of 1 to 31 ng chromium per mL have been reported. Tissue uptake is rapid with plasma clearance occurring 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. 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.

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 (TPN), 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.

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

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

## INDICATIONS AND CLINICAL USE

Micro Cr (Chromic Chloride Injection USP) is indicated as a supplement to intravenous solutions given for TPN. Its administration in TPN solutions helps to maintain plasma chromium levels and to prevent depletion of endogenous stores of chromium and subsequent deficiency symptoms.

## WARNINGS

Micro Cr is a hypotonic solution which should be administered in admixtures only.

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

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

## PRECAUTIONS

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.

## ADVERSE REACTIONS

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

## OVERDOSAGE

Trivalent chromium is a relatively nontoxic element. 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.

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| For management of a suspected drug overdose, contact your regional Poison Control Centre immediately. |

## DOSAGE AND ADMINISTRATION

### Dosage

The suggested dosage ranges are :

**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**: For pediatric patients, 0.14 to 0.20 mcg chromium/kg/day is suggested as the additive dosage level.

**Administration**

Periodic monitoring of chromium plasma levels is suggested as a guideline for administration.

Serum levels of 1 to 31 ng/mL have been reported in healthy subjects.

**Micro Cr** is for intravenous use after dilution only.

## PHARMACEUTICAL INFORMATION

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| Proper Name: | Chromic Chloride |
| Chemical Name: | Chromium Chloride hexahydrate |
| Molecular Formula: | $CrCl_3$ $6H_20$ |
| Molecular Mass: | 266.5 g/mol |
| Description: | 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. |

**Dilution for Intravenous Use**

Aseptic addition of Micro Cr 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.

## DOSAGE FORMS, COMPOSITION AND PACKAGING

Micro Cr contains 4 mcg/mL of chromium as chromic chloride hexahydrate in water for injection, with hydrochloric acid for pH adjustment.

Available in single use vials of 10 mL, boxes of 10.

The chlorobutyl rubber stopper is not made with natural rubber latex.

**STORAGE AND STABILITY**

Store between 15 and 28ºC. Protect from freezing.

## REFERENCES


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