

Trace Elements		
Composition		
Each mL contains		
<i>Active ingredients:</i>		
Ferrous chloride (iron(II) chloride · 4H ₂ O) (equivalent to 35.0 µmol of Iron)	695.8	µg
Zinc chloride (equivalent to 50.0 µmol of Zinc)	681.5	µg
Manganese chloride (equivalent to 10.0 µmol of manganese)	197.9	µg
Cupric chloride (equivalent to 12.0 µmol of copper)	204.6	µg
Chromic chloride (equivalent to 0.2 µmol of chromium)	5.3	µg
Sodium molybdate dihydrate (equivalent to 0.1 µmol of molybdenum)	2.42	µg
Sodium selenite pentahydrate (equivalent to 0.3 µmol of selenium)	7.89	µg
Sodium fluoride (equivalent to 30.0 µmol of fluorine)	126.0	µg
Potassium iodide (equivalent to 1.0 µmol of iodine)	16.6	µg

Tracutil

Excipients:
Hydrochloric acid, water for injections.

Pharmaco-therapeutic group
Additive to i.v. solutions for trace element replacement.

Indications
Tracutil is used as part of intravenous nutrition providing a source of trace elements for adult patients.

- Contraindications**
- Tracutil must not be administered to neonates, infants and children (due to lack of specific studies).
 - Pronounced cholestasis (serum bilirubin >140 mmol/L and elevated levels of gamma-glutamyltransferase and alkaline phosphatase)
 - Hypersensitivity to any of the ingredients of Tracutil.
 - Wilson's disease and disturbed iron storage (i.e. haemosiderosis or haemochromatosis).

Precautions for use and special warnings
Manganese blood levels should be regularly monitored in case of prolonged artificial nutrition. Dose reduction may be necessary, or Tracutil infusion should be stopped, if manganese accumulates.

Tracutil should be used with caution in case of impaired liver function, which may impair the biliary elimination of manganese, copper and zinc, leading to accumulation and overdose.

This trace element solution should be used with caution in case of impaired renal function, as excretion of some trace elements (selenium, fluoride, chromium, molybdenum and zinc) may be significantly decreased.

To prevent iron overload, which is a risk mainly in patients with impaired liver function or those receiving blood transfusions, serum ferritin levels should be monitored at regular intervals.

In patients undergoing medium to long term parenteral nutrition, there is an increased frequency of zinc and selenium deficiency. In such circumstances, especially in the presence of hypercatabolism, e.g. after massive trauma, major surgery, burns etc., when necessary the dosage should be adapted and an extra supply of these elements should be provided.

Tracutil should be given with caution in cases of manifest hyperthyroidism or sensitivity to iodine if other iodine containing medicinal products (e.g. iodine antiseptics) are administered concomitantly.

Chromium deficiency leads to a decrease in glucose tolerance, which improves after chromium supplementation. Then in diabetic patients on insulin medication, relative overdose of insulin and consecutive hypoglycaemia may result. Therefore checks of the blood glucose levels are recommended. Re-adjustment of the insulin doses may become necessary.

Pregnancy and lactation
No safety data for Tracutil are available when it is administered during pregnancy and lactation. Therefore, this product should not be used during pregnancy and lactation except after careful consideration of its expected benefits and potential risks.

Interactions
The degradation of vitamin C in solutions for infusion is accelerated in the presence of trace elements.

Tracutil must not be used as a diluent for other drugs.

The compatibility with solutions administered simultaneously via a common inlet cannula must be ensured.

Tracutil cannot be added directly to inorganic phosphate (additive) solutions. In case of addition to complex nutritive mixtures containing inorganic phosphate, please refer to the manufacturer.

The product should not be added to alkaline solutions with marked buffer capacity, e.g. sodium bicarbonate solutions.

Do not add to fat emulsions.

Complete information about incompatibilities is not available. Please refer to the manufacturer for further information.

Dosage
For adults only.

Recommended dosage schedule
The recommended daily dose in patients with basal requirements is 10 mL (1 ampoule).

In patients with moderately increased requirements the daily dose may be up to 20 mL (2 ampoules), accompanied by monitoring of the trace element status.

In cases of significantly increased trace element requirements (such as extensive burns, severe hypercatabolic polytraumatic patients) higher doses may be necessary.

The doses for patients with impaired liver and/or kidney function should be determined individually. For these patients lower doses may be required.

Administration can be continued for the duration of parenteral nutrition.



293/12611268/1012



Directions for User

Tracutil

B | BRAUN

B. Braun Melsungen AG
34209 Melsungen
Germany



schwarz

Dokument = 210 x 298 mm
2 Seiten

Lätus



407

293/12611268/1012 - PH
Tracutil
L03
GIF (GA)
Standort Berlin

G 101564

Method of administration

Tracutil, which is a trace element concentrate, should only be administered intravenously after dilution with not less than 250 mL of a suitable solution for infusion, for example:

- glucose solutions (5 % or 10 % w/v),
- electrolyte solutions (e.g. sodium chloride 0.9%, Ringer’s solution).

Compatibility must be tested before addition to other infusion solutions. The infusion of the ready-to-use mixture should not take less than 6 hours and should be completed within 24 hours.

Further information, see Instructions for storage / use / handling.

Notes:

Diarrhoea may lead to increased intestinal loss of zinc. The serum concentrations must be checked in this case.

Deficiencies of individual trace elements must be corrected by specific supplementation.

Overdose

No cases of overdosing have been reported.

Undesirable effects

There are isolated reports of anaphylactic reactions to parenterally administered iron with possible fatal outcome.

Iodine may cause allergic reactions.

Note

Patients should inform their doctor or pharmacist if they experience any adverse reaction not mentioned in this leaflet.

Expiry date

The product must not be used beyond the expiry date stated on the labelling.

Instructions for use / handling

Tracutil can be diluted in not less than 250 mL of 5 %, 10 %, 20 %, 40 % or 50 % glucose solutions or electrolyte solutions e.g. 0.9 sodium chloride or Ringer’s solution.

Addition to the diluent solution should be performed under strict aseptic conditions.

Only to be used if solution is clear and container undamaged.

Discard unused contents of an opened ampoule.

Shelf life after reconstitution:

Chemical and physical in-use stability 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 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Caution

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Storage

Store at temperatures not exceeding 25°C.

Availability

Concentrated solution for infusion in glass ampoules, contents: 10 mL

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Date of last revision

11.2000

Manufactured by:

B. Braun Melsungen AG
34209 Melsungen, Germany

Imported by:

B. Braun Medical Supplies, Inc.

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