Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

293/12610275/0111

Tracutil

B. Braun Melsungen AG
34209 Melsungen, Germany

Composition

1 ampoule of 10 ml contains

Active ingredients:

Ferrous chloride (iron(II) chloride · $4H_2O$)	6.958 mg
Zinc chloride	6.815 mg
Manganese chloride	1.979 mg
Cupric chloride	2.046 mg
Chromic chloride	0.053 mg
Sodium molybdate dihydrate	0.0242 mg
Sodium selenite pentahydrate	0.0789 mg
Sodium fluoride	1.260 mg
Potassium iodide	0.166 mg

Trace element content per ampoule

Iron	2.0	mg or	35	µmol
Zinc	3.3	mg or	50	µmol
Manganese	550	µg or	10	µmol
Copper	760	µg or	12	µmol
Chromium	10	µg or	0.2	µmol
Molybdenum	10	µg or	0.1	µmol
Selenium	24	µg or	0.3	µmol
Fluorine	570	µg or	30	µmol
Iodine	127	µg or	1	µmol

Excipients:
Hydrochloric acid, water for injections.

Pharmaceutical form

Concentrate for solution for infusion in glass ampoules, contents: 10 ml

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, mobybdenum 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.

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2 Seiten

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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.

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
Overdose with Tracutil is extremely unlikely since the quantity of trace elements per ampoule is well below known toxic levels. If overdose is suspected, treatment with Tracutil should be discontinued. Overdose can be confirmed by appropriate laboratory tests.

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 storage / 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.

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10.2000