Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

Nutritrace

Concentrate for solution for infusion

Composition
The concentrate for solution for infusion contains

Active substance	*per 1 ml*
Iron(II) chloride tetrahydrate	695.8 micrograms
Zinc chloride	681.5 micrograms
Manganese(II) chloride tetrahydrate	197.9 micrograms
Copper(II) chloride dihydrate	204.6 micrograms
Chromium(III) chloride hexahydrate	5.3 micrograms
Sodium selenite pentahydrate	7.89 micrograms
Sodium molybdate dihydrate	2.42 micrograms
Potassium iodide	16.6 micrograms
Sodium fluoride	126.0 micrograms

Trace element content	*Micromoles/ampoule*	*Micrograms/ampoule*
Iron	35 micromoles	2000 micrograms
Zinc	50 micromoles	3300 micrograms
Manganese	10 micromoles	550 micrograms
Copper	12 micromoles	760 micrograms
Chromium	0.2 micromoles	10 micrograms
Selenium	0.3 micromoles	24 micrograms
Molybdenum	0.1 micromoles	10 micrograms
Iodine	1.0 micromoles	127 micrograms
Fluorine	30 micromoles	570 micrograms

Excipients:
Hydrochloric acid and water for injections

Pharmaceutical form and contents
Concentrate for solution for infusion

Glass ampoules containing 10 ml
Clear colourless aqueous solution

Theoretical osmolarity, approximately 90 mOsm/l
pH 1.7 – 2.3

Pharmacotherapeutic group
Additives to i.v. solutions
ATC code: B05X

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

Contraindications
- Hypersensitivity to the active substances or to any of the excipients of Nutritrace
- Pronounced cholestasis (serum bilirubin >140 mmol/l and elevated levels of gamma-glutamyltransferase and alkaline phosphatase)
- Wilson's disease and disturbed iron storage (i.e. haemosiderosis or haemochromatosis)
- Administration to neonates, infants and children (due to lack of specific studies).

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

Nutritrace 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.

Nutritrace 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.

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.

Interaction with other medicinal products and other forms of interaction
Interactions with other medicinal products have not become known so far.

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

Do not add to lipid emulsions.

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

293/12391791/0413

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Concentrate for solution
for infusion

B. Braun Melsungen AG
34209 Melsungen
Germany

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Dokument = 210 x 298 mm
2 Seiten

Lätus
699

293/12391791/0413 – SG
Nutritrace
L03
GIF (GA)
Standort Berlin

Schriftgröße: 9,5 Punkt

G 120960

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Nutritrace cannot be added directly to inorganic phosphate (additive) solutions.

It is not possible to present complete information about incompatibilities in this section. Please refer to the marketing authorisation holder for further information.

Fertility, Pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of Nutritrace in pregnant women. Reproductive and developmental toxicity studies in animals have not been performed with Nutritrace. Therefore, Nutritrace should not be used during pregnancy except after careful consideration of its expected benefits and potential risks.

Breast-feeding
It is unknown whether the components of Nutritrace are excreted in human milk Nutritrace should be used during lactation only after careful consideration of its expected benefits and potential risks.

Fertility
No data available.

Effects on ability to drive and use machines
Nutritrace has no influence on the ability to drive and use machines.

Dosage

Adults
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 patients with multiple traumas) higher doses may be necessary.

Paediatric population
Nutritrace must not be used in neonates, infants and children (see section contraindications).

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

Method of administration
Intravenous use.

Precautions to be taken before handling or administering the medicinal product

Nutritrace, 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 examples:
– glucose solutions (glucose 5% or 10% w/w)
– 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 "Instruction for disposal/storage/use/handling".

Duration of use
Administration can be continued for the duration of parenteral nutrition.

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

Undesirable effects

Immune system disorders
There are isolated reports of anaphylactic reactions to parenterally administered iron with possible fatal out-come (frequency: not known)
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. The expiry date refers to the last date of that month.

Instructions for disposal /storage / use / handling
No special requirements for disposal.

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

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

Nutritrace can be diluted in not less than 250 ml of:
- Glucose 50 mg/ml / 100 mg/ml / 200 mg/ml / 400 mg/ml / 500 mg/ml solutions for infusion, or
- Electrolyte solutions, e.g. sodium chloride 9 mg/ml solution for infusion or Ringer's solution for infusion.

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

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

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

The ampoules are for single use only. After use discard ampoule and remaining content.

Shelf life after reconstitution:
Chemical and physical in-use stability of dilutions has been demonstrated for 24 hours at 25 ° C. From a microbiological point of view, the diluted 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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