

NAME OF THE MEDICINAL PRODUCT

Tracutil Concentrate for solution for infusion

COMPOSITION

Each 1 ml of the concentrate for solution for infusion contains:

	Micrograms per 1 ml
Ferrous chloride	695.8
Zinc chloride	681.5
Manganese chloride	197.9
Cupric chloride	204.6
Chromic chloride	5.3
Sodium selenite pentahydrate	7.89
Sodium molybdate dihydrate	2.42
Potassium iodide	16.6
Sodium fluoride	126.0

Each ampoule of 10 ml contains:

<i>Trace element content</i>	<i>Micromoles per ampoule</i>	<i>Micrograms per ampoule</i>
Iron	35	2 000
Zinc	50	3 300
Manganese	10	550
Copper	12	760
Chromium	0.2	10
Selenium	0.3	24
Molybdenum	0.1	10
Iodine	1.0	127
Fluorine	30	570

Excipient with known effect:

Each 10 ml ampoule contains 147 micromoles (or 3.4 mg) of sodium.

List of excipients:

Hydrochloric acid (for pH-adjustment) and Water for injections.

THERAPEUTIC INDICATIONS

Tracutil 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
- 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)

Tracutil is contraindicated in neonates, infants and children as its composition is not suitable for this age group.

UNDESIRABLE EFFECTS

Undesirable effects are listed according to their frequencies as follows:

Not known: (cannot be estimated from the available data)

System organ class

Immune system disorder

Not known: Anaphylactic reactions to parenterally administered iron, with possible fatal outcome.
Iodine may cause allergic reactions.

WARNINGS

Keep out of the sight and reach of children.

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

NOTE

Prescription only

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

B. Braun Melsungen AG, 34209 Melsungen, Germany, 11/2012

Title: Tracutil Initiator: Roxana ? Tranca

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