PACKAGE LEAFLET: INFORMATION FOR THE USER

B. Braun Melsungen AG · 34209 Melsungen, Germany

Tracutil Concentrate for Solution for Infusion Electrolytes and trace elements

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tracutil is and what it is used for

Tracutil is a concentrate which is diluted prior to use in a suitable solution for infusion.

It is a solution for providing trace elements used during parenteral nutrition (nutrition via a venous catheter) in adult patients.

2. What you need to know before you use Tracutil

Do not use Tracutil,
- If you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6)
- If you have pronounced cholestasis (with reduced bile flux) and abnormal liver function tests
- If you suffer from Wilson's disease (disturbed copper elimination) or certain types of iron storage disorders (haemosiderosis, haemochromatosis).

Tracutil must not be administered to newborn babies, infants and children.

Warnings and precautions:

Talk to your doctor before using Tracutil
- If you have impaired liver function which may impair the excretion of manganese, copper and zinc. Your dose may have to be reduced.
- If you have impaired kidney function, because excretion of selenium, fluoride, chromium, molybdenum and zinc may be significantly decreased.
- If you have increased thyroid activity.
- If you are hypersensitive to iodine

Various tests may be performed while you are given this medicine to ensure that none of the elements that Tracutil contains accumulate excessively in the body.

If you have impaired liver function or receive blood transfusions your blood should be monitored regularly for the concentration of a specific iron-storage protein (serum ferritin levels) to prevent an iron overload.

In patients undergoing medium to prolonged Tracutil treatment zinc and selenium deficiency may develop. Your doctor will adapt your Tracutil dose accordingly or you will be given additional supplements.

Correcting a chromium deficiency leads to an improvement in glucose utilisation. This must be taken into account in patients with insulin-dependent diabetes. Readjustment of the insulin doses may become necessary.

Children and adolescents

This medicine must not be used in newborn babies, infants and children, since its composition is not suitable for this age group. (see section "Do not use Tracutil"). The use of this medicine in adolescence is not recommended.

Other medicines and Tracutil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

There are no or limited amount of data from the use of this medicine in pregnancy. Tracutil should not be given during pregnancy unless the clinical condition of the woman requires treatment with Tracutil.

Breast-feeding

It is unknown whether the components of Tracutil are excreted in human milk. Your doctor will therefore weigh up very carefully whether this medicine is appropriate for you.

Driving and using machines

This medicine is normally given to immobile patients in a controlled setting. This will exclude driving and using machines.

Tracutil contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 10 ml dose; i.e. it is essentially 'sodium-free'.

3. How to use Tracutil

This medicine will be given to you by a healthcare professional.

The recommended dose is:

Your doctor will decide on the dose that is right for you.

For normal requirements adults will receive 1 ampoule Tracutil per day and for moderately increased requirements up to 2 ampoules.

If the requirement is much greater (such as in patients with higher energy requirements e.g. after serious injuries, burns or major surgery) higher doses may also be needed.

If you have a liver or kidney disease your dose may be reduced where this is appropriate.

Method of administration

Tracutil will be given by infusion (intravenous drip) after it has been diluted in a suitable solution for infusion.

If you received more Tracutil than you should

An overdose is very unlikely as the amount of trace elements contained in Tracutil is far below values that could be toxic. Yet if an overdose is suspected, administration of Tracutil should be discontinued. An overdose can be confirmed by appropriate laboratory tests.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Tracutil can cause side effects, although not everybody gets them.

If you notice any of the following side effects please tell your doctor without delay:

Not known (frequency cannot be estimated from the available data)
Allergic (anaphylactic) reactions to iron given intravenously, with possible fatal outcome.

Iodine may cause allergic reactions.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via the following:
United Kingdom
Yellow Card Scheme
www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tracutil

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the ampoule and carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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

6. Contents of the pack and other information

What Tracutil contains

The active substances are salts of trace elements:

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

Trace element content	Micromoles/ampoule	Micrograms/ampoule
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

The other ingredients are hydrochloric acid (for pH adjustment) and water for injections.

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Electrolytes and trace elements

B. Braun Melsungen AG
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Germany

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What Tracutil looks like and contents of the pack

Tracutil is a clear, colourless, aqueous solution.
Tracutil is supplied in 10 ml glass ampoules.
Tracutil is available in packs containing 5 or 50 glass ampoules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Tracutil
Denmark:	Nutritrace
Finland:	Nutritrace
France:	Tracutil
Great Britain:	Tracutil
Italy:	Olitrace
Luxembourg:	Tracutil
Netherlands:	Nutritrace
Austria:	Tracutil
Spain:	OligoPlus

This leaflet was last revised in June 2013

The following information is intended for healthcare professionals only:

Monitoring measures

It is recommended to monitor the levels of trace elements included in this medicinal product and other parameters on a regular basis during the treatment with Tracutil.
For details please refer to section 4.4. of the Summary of Product Characteristics.

Incompatibilities

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

Do not add to fat emulsions.

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

Tracutil should not 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.

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6 of the SmPC.

Method and duration of administration

Tracutil is a concentrate for solution for infusion. It should only be administered intravenously after dilution with not less than 250 ml of a suitable solution for infusion. Suitable carrier solutions include for example
– glucose solutions (glucose 5% w/v, 10% w/v, 20% w/v, 40% w/v, 50% w/v)
– electrolyte solutions (e.g. sodium chloride 0.9% w/v, Ringer's solution)

A compatibility test must be performed before it is added to other infusion solutions.

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

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

Tracutil must not be used as a diluent for other medicinal products.

The infusion of the ready-to-use mixture should not take less than 6 hours and should be completed within 24 hours.

Administration can be continued for the duration of parenteral nutrition.

Notes:
Diarrhoea may lead to increased intestinal loss of zinc. The serum concentrations must be checked in this case.
Deficiencies of individual trace elements should be corrected by specific supplementation.

Shelf life after dilution

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.