Fresenius Kabi

1. TRADE NAME OF THE MEDICINAL PRODUCT

ADDAMEL N

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of ADDAMEL N contains:

Active ingredients	Quantity
Chromic chloride 6 H_2O	5.33 µg
Copper chloride 2 H_2O	0.34 mg
Ferric chloride 6 H_2O	0.54 mg
Manganese chloride 4 H_2O	99.0 µg
Potassium iodide	16.6 µg
Sodium fluoride	0.21 mg
Sodium molybdate 2 H_2O	4.85 µg
Sodium selenite (Anhydrous)	6.90 µg
Zinc chloride	1.36 mg

The active ingredients in 1 ml of ADDAMEL N correspond to:

Cr	0.02	µmol
Cu	2	µmol
Fe	2	µmol
Mn	0.5	µmol
I	0.1	µmol
F	5	µmol
Mo	0.02	µmol
Se	0.04	µmol
Zn	10	µmol

The content of sodium and potassium correspond to

Sodium	118 µg	5.12 µmol
Potassium	3.9 µg	0.1 µmol

PRODUCT PROPERTIES

- Osmolality: approx. 3100 mosm/kg water
- pH: To approx. 2.5

3. PHARMACEUTICAL FORM

Concentrate for solution for infusion

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Addamel N is indicated as a supplement in intravenous nutrition of adults to meet the requirements of trace elements.

4.2 Posology and method of administration

ADDAMEL N must not be given undiluted.

The recommended daily dosage of ADDAMEL N in adult patients with basal to moderately increased requirements is 10 ml (one ampoule).

4.3 Contraindications

Total biliary obstruction.

4.4 Special warnings and special precautions for use

ADDAMEL N should be used with caution in patients with impaired biliary and/or renal function in whom the excretion of trace elements may be significantly decreased.

ADDAMEL N should also be used with caution in patients with biochemical or clinical evidence of liver dysfunction (especially cholestasis).

If the treatment is continued for more than 4 weeks, checking of manganese levels is required.

Use solutions containing sodium ions cautiously in patients with CHF and edema with sodium retention. Use solutions containing potassium ions cautiously in patients with hyperkalemia and in conditions in which potassium retention is present. Adjust reduce or omit trace metal supplements in GI malfunction. Consider contributions from blood transfusions, frequently determine plasma levels.

Wilson's disease: Avoid administering copper supplements to patients with genetic disorder of copper metabolism/

ADDAMEL N must not be given undiluted.

4.5 Interaction with other medicaments and other forms of interaction

No interactions with other drugs have been observed.

4.6 Pregnancy and lactation

Animal reproduction studies or clinical investigations during pregnancy have not been carried out with ADDAMEL N. However, the requirements of trace elements in a pregnant woman are slightly increased compared to non-pregnant women.

No adverse events are to be expected when ADDAMEL N is administered during pregnancy.However give to a pregnant woman only if clearly indicated. Molybdenum crosses the placenta.

4.7 Effects on ability to drive and use machines

No effects on the ability to drive and use machines are to be expected.

4.8 Undesirable effects

No adverse effects related to the trace elements in ADDAMEL N have been reported.

Superficial thrombophlebitis has been observed when glucose containing ADDAMEL N was given. However, it is not possible to deduce whether this reaction is attributable to the infused trace elements or not.

Allergic reactions to iodine may occur following topical application. No adverse reactions are known to occur as a consequence of using the recommended intravenous iodide dosage levels.

4.9 Overdose

In patients with impaired renal or biliary function, there is an increased risk for accumulation of trace elements.

In case of a chronic overload of iron there is a risk of haemosiderosis, which in severe and rare cases can be treated by venesection.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ADDAMEL N is a mixture of trace elements in amounts normally absorbed from the oral diet and should have no pharmacodynamic effect besides maintaining or repleting the nutritional status.

5.2 Pharmacokinetic properties

When infused intravenously, the trace elements in ADDAMEL N are handled in a similar way to trace elements from an oral diet. Individual trace elements will be taken up by tissues to different extents, depending on the requirements within each tissue to maintain or restore the concentration of each element for the metabolic requirements of that tissue.

Copper and manganese are normally excreted via the bile, whereas selenium, zinc and chromium (especially in patients receiving intravenous nutrition) are mainly excreted via the urine.

The main route of molybdenum excretion is the urine, although small amounts are excreted in the bile.

Iron is eliminated in small amounts by superficial loss and desquamation of gut cells. Premenopausal women can lose 30-150 mg of iron in the monthly blood loss. Iron excretion follows all kinds of bleedings.

5.3 Preclinical safety data

The safety evaluation is based mainly on clinical experience and documentation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Other ingredients	Quantity	Reference to standards
Xylitol	300 mg	Ph. Eur. + USP
Hydrochloric acid 1 M	to pH 2.2	Ph. Eur.
Water for injections	to 1 ml	Ph. Eur.

6.2 Incompatibilities

ADDAMEL N may only be added to or mixed with other medicinal products for which compatibility has been documented. See 6.6.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25°C. Do not freeze.

6.5 Nature and contents of container

Ampoule,polypropylene
Pack size: 20 x 10 ml

6.6 Instructions for use/handling

ADDAMEL N must not be given undiluted.

COMPATIBILITY

Additions should be made aseptically.

Up to 20 ml ADDAMEL N can be added to 1000 ml Vamin Glucose, Vamin 14 Electrolyte Free, Vamin 18 Electrolyte Free and glucose solutions 50 mg/ml-500 mg/ml.

STABILITY

When additions are made to an infusion solution, the infusion should be completed within 24 hours from preparation to prevent microbiological contamination. The left over contents of opened bottles/vials/ampoules should be discarded and not kept for later use.

Manufactured by:
Fresenius Kabi Norge AS, Halden, Norway for Fresenius Kabi AB, Uppsala, Sweden

Registration Holder:
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