SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Peditrace Concentrate for Infusion Solutions

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Zinc chloride	521 µg
Copper chloride 2 H_2O	53.7 µg
Manganese chloride 4 H_2O	3.60 µg
Sodium selenite anhydrate	4.38 µg
Sodium fluoride	126 µg
Potassium iodide	1.31 µg

The active ingredients in 1 ml Peditrace are equivalent to the following:

Zn	250 µg	3.82 µmol
Cu	20 µg	0.315 µmol
Mn	1 µg	18.2 nmol
Se	2 µg	25.3 nmol
F	57 µg	3.00 µmol
I	1 µg	7.88 nmol

Osmolality: 38 mOsm per kg water
pH: 2,0

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

To cover basal trace element needs for neonates and children receiving total intravenous nutrition.

4.2 Posology and method of administration

Must be diluted. See section 6.6 “Special precautions for use, disposal and other handling”.
1 ml Peditrace per kg of body weight per day for infants and children weighing up to 15 kg. For children weighing 15 kg or more, a daily dose of 15 ml Peditrace covers the basal need of trace elements. The infusion duration should be at least 8 hours.

4.3 Contraindications

Wilson's disease.

4.4 Special warnings and precautions for use

Peditrace 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.
Peditrace should also be used with caution in patients with biochemical or clinical evidence of liver dysfunction (especially cholestasis). Trace element levels in plasma must be monitored in patients with cholestatic liver disease and renal insufficiency.
If treatment lasts more than 4 weeks, manganese levels must be checked.
If intravenous nutrition is administered for a prolonged period of time (month), plasma levels of trace elements should also be monitored.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction with other medicinal products has been observed.

4.6 Pregnancy and lactation

Not relevant.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

No side effects related to the trace elements in Peditrace have been reported.

4.9 Overdose

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5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Electrolytes in combination with other drugs, ATC code: B05XA31

Peditrace is a mixture of trace elements in amounts normally absorbed from the oral diet and should have no pharmacodynamic effect besides maintaining or repleting nutritional status. Iron is not included.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

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6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid
Water for injection solution

6.2 Compatibility

Peditrace may only be added to or mixed with other medicinal products for which compatibility has been documented. See section 6.6 “Special precautions for use, disposal and other handling”.

6.3 Shelf life

3 years.
If addition to the infusion solution is made on the ward, the infusion should be used immediately due to the risk of contamination. The contents of opened bottles must be discarded, and must not be saved for later use. If addition is done using stringent aseptic techniques in an environmental bench, the mixture must be used within 96 hours. The mixture must be stored at 2-8°C and infused within 24 hours of being removed from cold storage.

6.4 Special precautions for storage

Store at a maximum of 25°C. Do not freeze.

6.5 Nature and contents of container

Injection bottle, polypropylene plastic.
Container size: 10 x 10 ml

6.6 Special precautions for use, disposal and other handling

Additions must be made aseptically.

Compatibility
Up to 6 ml Peditrace can be added to 100 ml Vaminolac, Vamin 14 g N/l electrolyte free or glucose solution 50-500 mg/ml.

Data on addition to mixtures in phthalate-free bag and for addition to TPN solutions is available upon request from the manufacturer.

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi AB
SE-751 74 Uppsala, Sweden

8 MARKETING AUTHORISATION NUMBER

11747

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1993-02-05/2008-02-05

10 DATE OF REVISION OF THE TEXT

2009-05-13