Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Peditrace concentrate for solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of Peditrace contains:

Zinc chloride	521	micrograms
Copper chloride $2H_2O$	53.7	micrograms
Manganese chloride $4H_2O$	3.60	micrograms
Sodium selenite anhydrous	4.38	micrograms
Sodium fluoride	126	micrograms
Potassium iodide	1.31	micrograms

The active ingredients in 1 ml correspond to:

Zinc	250	micrograms	3.82	micromol
Copper	20	micrograms	0.315	micromol
Manganese	1	micrograms	18.2	nmol
Selenium	2	micrograms	25.3	nmol
Flouride	57	micrograms	3.0	micromol
Iodine	1	micrograms	7.88	nmol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion
A sterile, clear, colourless solution for addition to certain infusion fluids.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Peditrace is intended to meet the basal requirements for trace elements during intravenous nutrition of infants and children.

4.2 Posology and method of administration

Posology

Paediatric population
The basal requirements for infants and children of the included trace elements are met by 1 ml of Peditrace per kg body weight per day to a maximum daily dose of 15 ml. A daily dose of 15 ml Peditrace should also meet the basic needs of trace elements in children weighing 15-40 kg. Above 40 kg the adult preparation Additrace should be used.

<u>Method of administration</u>
Peditrace should not be given undiluted.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

Wilson's disease.

Administration should be carried out but only under specialist surveillance, especially in patients with pre-existing imbalances, in renal failure or hepatic disease.

4.4 Special warnings and precautions for use

Peditrace should be used with caution in conditions where excretion in the bile is reduced, particularly when cholestatic liver disease is present and/or when urinary excretion is markedly reduced.

Patients with such conditions require careful biochemical monitoring as the excretion of trace elements may also be significantly decreased. (Copper and manganese being normally excreted in bile; selenium and zinc, especially in patients receiving parenteral nutrition, being excreted mainly in the urine)

Patients requiring long term total parenteral nutrition (TPN) (defined as longer than one month) should have a baseline whole blood or serum manganese level within or below the normal range and normal liver function before receiving Peditrace.

Manganese levels and liver function should be monitored regularly (monthly) while the patient is maintained on Peditrace.

Peditrace should be stopped if manganese levels rise into the potentially toxic range (please refer to appropriate reference ranges for the testing laboratory), or if cholestasis develops.

Addition of other drugs to be avoided due to the risk of precipitation. A cloudy solution or one containing a precipitate must not be used.

4.5 Interaction with other medicinal products and other forms of interactions

No interactions with other drugs have been observed.

4.6 Fertility, pregnancy and lactation

Not relevant

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Impaired renal or hepatic excretion may lead to chronic overdose of one or more trace elements.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected

adverse reactions via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

In recommended doses Peditrace supplies trace elements at the level of normal daily requirements.

Acute
Acute overdose of these trace elements is unlikely to be hazardous.

Chronic
Chronic overdose of manganese has been recorded as causing Parkinsonism and psychosis.

Chronic overdosage may very rarely occur secondary to an unsuspected idiosyncratic deficiency in metabolism or excretion for a specific trace element. In this case, signs may be observed such as nail dystrophy with insidious onset of symptoms secondary to haematological changes or tissue deposition. Diagnosis would be confirmed by biochemical and haematological tests and treatment should be withdrawal of Peditrace.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Combination of electrolytes, Electrolytes in combination with other drugs
ATC code: B05XA30, B05XA31

The maintenance of nutritional status in paediatric patients is the main pharmacodynamic effect of Peditrace.

5.2 Pharmacokinetic properties

The trace elements in Peditrace, infused in physiological amounts, should be utilised in the same way as elements absorbed from an oral diet.

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

No toxic effects were observed during the preclinical studies.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid
Water for injections

6.2 Incompatibilities

Addition of drugs to Peditrace, or Peditrace to infusion solutions may only be made when the compatibility is established.

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

2 years in polypropylene of Atofina 3021 SM3 resin.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

Store the vial in the outer carton.

6.5 Nature and contents of container

Polypropylene plastic vial with rubber stopper and flip-off cap.

Pack size 10 x 10 ml.

6.6 Special precautions for disposal and other handling

Peditrace must be diluted before administration.

Use in the paediatric population.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352
Germany

8 MARKETING AUTHORISATION NUMBER

PA2059/051/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 November 1995

Date of last renewal: 13 November 2005

10 DATE OF REVISION OF THE TEXT

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