SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Peditrace

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of Peditrace contains:

Active Ingredients	Quantity
Zinc Chloride	521 µg
Copper Chloride $2H_20$	53.7 µg
Manganese Chloride 4 H_20	3.60 µg
Sodium Selenite anhydrous	4.38 µg
Sodium Fluoride	126 µg
Potassium Iodide	1.31 µg

The active ingredients in 1 ml correspond to

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

Product Properties

Osmolality:	38 mosm/kg water
pH:	2.0

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Peditrace is indicated to meet the basal requirement of trace elements during intravenous nutrition of infants and children.

4.2 Posology and method of administration

Peditrace must not be given undiluted.

The recommended dose is 1 ml Peditrace/kg body weight/day for infants and children with a weight of up to 15 kg. The basic requirements of trace elements are covered by a daily dose of 15 ml to children weighing more than 15 kg.

4.3 Contraindications

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

Wilson's disease.

4.4 Special warnings and precautions for use

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

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.

4.5. Interactions with other Medicaments and other forms of Interaction

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

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website (www.health.gov.il) which links to an online form for reporting side effects, or by following this link: https://sideeffects.health.gov.il and by emailing the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

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

Peditrace is a concentrated trace element solution formulated to cover the requirements of neonates and infants receiving total parenteral nutrition. Potassium magnesium and calcium are not included in the formulation as individual requirements vary from patient to patient.

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.

No pharmacokinetic studies with Peditrace have been performed.

5.3. Preclinical Safety Data

No toxic effects were observed during the pre-clinical studies.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid
Water for injections

6.2. Incompatibilities

Do not add drugs with Peditrace to infusion solution unless the compatibility profile is satisfactory.

Do not add Peditrace to infusion solutions other than those recommended unless the compatibility profile is satisfactory.

6.3. Shelf Life

The expiry date of the product is indicated on the packaging materials.

6.4. Special Precautions for Storage

Do not freeze. Store below 25°C.

6.5. Nature and Contents of Container

Polypropylene plastic vial with rubber stopper.
Pack sizes: 10 x 10 ml

6.6 Special precautions for disposal

Compatibility

Additions should be made aseptically.

Additions

Up to 6 ml Peditrace can be added to 100 ml Vaminolact, Vamin 9 Electrolyte Free, Vamin 14 Electrolyte Free or glucose solution (50-500 mg/ml).

Infusion time

The infusion time should not be less than 8 hours. The infusion should be given at a very slow rate.

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.

7 MANUFACTURER

Fresenius Kabi AB, Uppsala, Sweden

8 REGISTRATION HOLDER

Cure Medical & Technical Supply Ltd, Hashiloach 6, P.O.B. 3340, Petach Tikva.

9 REGISTRATION NUMBER(S)

104-30-28847

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