DATA SHEET

NAME OF MEDICINE
PEDITRACE™
Concentrate for solution for infusion

PRESENTATION
Peditrace is a clear, colourless solution with a pH of 2.0 and an osmolality of 38 mOsm/kg water.

Each mL contains:

Copper chloride (dihydrate) 53.7 μg	= 20 μg/0.315 μmol Cu
Manganese chloride (tetrahydrate) 3.6 μg	= 1 μg/18.2 nmol Mn
Potassium iodide 1.31 μg	= 1 μg/7.88 nmol I
Sodium fluoride 126 μg	= 57 μg/3.0 μmol F
Sodium selenate (anhydrous) 4.38 μg	= 2 μg/25.3 nmol Se
Zinc chloride 521 μg	= 250 μg/3.82 μmol Zn

It also contains:

Sodium 70 μg/mL	= 3.05 μmol/mL
Potassium 0.31μg/mL	= 7.88 nmol/mL

USES
Actions
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.

Pharmacokinetics
When infused intravenously the trace elements in Peditrace 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 requirement within each tissue to maintain or restore the concentration of each element for the metabolic requirement of that tissue.

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.

INDICATIONS
Peditrace is indicated in premature and full-term infants and children needing intravenous nutrition to supply the basal requirements of trace elements.

DOSAGE AND 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.

Compatibility
Additions should be made aseptically.

Additions
Up to 6 mL Peditrace can be added to 100 mL Vaminolact, 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.

CONTRAINDICATIONS
Wilson's Disease.

WARNINGS AND PRECAUTIONS
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).

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

Patients with increased losses or requiring prolonged intravenous nutrition should be monitored biochemically to confirm the requirements are being met appropriately.

Use in pregnancy and lactation
Not applicable.

Effects on ability to drive and use machines
Peditrace is unlikely to produce an effect on the ability to drive and use machines.

ADVERSE REACTIONS
No adverse effects related to the trace elements in Peditrace have been reported.

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

Interactions
No interactions with other drugs have been observed.

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

PHARMACEUTICAL PRECAUTIONS
Shelf-life: 3 years

STORAGE
Store below 25°C, do not freeze.

PACKAGE QUANTITIES
Vial for injection, polypropylene plastic

Pack size: 10 X 10 mL

MEDICINES CLASSIFICATION
General Sale Medicine

FURTHER INFORMATION
Other excipients are hydrochloric acid and water for injections.

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