SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Peditrace concentrate for solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of Peditrace contains:

Active Ingredients	Quantity	Reference to Standard
Zinc Chloride	521µg	Ph.Eur.
Copper Chloride $2H_20$	53.7µg	USP
Manganese Chloride 4 H_20	3.60µg	USP
Sodium Selenite anhydrous	4.38µg	
Sodium Fluoride	126µg	Ph.Eur.
Potassium Iodide	1.31µg	Ph.Eur.

The active ingredients in 1 ml correspond to

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

Product Properties

Osmolality:	38 mosm/kg water
pH:	2.0

3 PHARMACEUTICAL FORM

Concentrate for infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Peditrace is an integral part of the complete intravenous nutrition of infants and children. It is intended to meet basal requirements for trace elements and

should be used in conjunction with amino acid or glucose solutions or other paediatric admixtures.

4.2 Posology and method of administration

Posology

Adults and elderly:

The trace element solution Additrace should be used in adults and elderly.

Paediatric population:

Infants and children (weighing 15 kg or less):

Basal requirements of the included trace elements are covered by 1 ml Peditrace per kg body weight per day to a maximum daily dose of 15 ml.

Children (weighing 15 kg or more):

A daily dose of 15 ml Peditrace should meet basal trace element requirements. However, for patients weighing more than 40 kg the adult preparation Additrace should be used.

Method of administration
Peditrace should not be given undiluted.

Peditrace administration should not be started until kidney function is established – usually during the second day of life.

The infusion should be given at a very slow rate (minimum infusion period is 8 hours) and is best done with an appropriate pump or an automatic drop rate counter.

As the requirements of trace elements may vary in different clinical conditions, these substances may have to be added as appropriate in the individual patient.

Potassium and sodium requirements also vary with different clinical conditions. Peditrace is not intended to meet these requirements.

Patients who are likely to lose higher than average amounts of trace elements, or those requiring prolonged intravenous nutrition should be monitored bio-chemically to confirm that requirements are being appropriately met.

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
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 directly via the Yellow card Scheme www.mhra.gov.uk/yellowcard.

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 shelf life is 36 months when stored in room temperature (below 25°C).

6.4. Special Precautions for Storage

Do not freeze. Protect vials from light. Store below 25°C.

6.5. Nature and Contents of Container

Polypropylene plastic vial with rubber stopper and flip-off caps.
Pack sizes: 10 x 10 ml

6.6 Special precautions for disposal

Must not be given undiluted. Peditrace can be added to either an amino acid solution or glucose solution (see below) and given during a minimum infusion period of 8 hours. The infusion should be given at a very slow rate and is best done with an appropriate pump or an automatic drop rate counter. Only admixtures in which compatibility has been documented are to be used.

The addition of Peditrace must be done aseptically within one hour before the start of infusion. To minimise the risk of infection the infusate should be used within 24 hours.

<u>Compatibility</u>

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

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

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 08828/0115

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31 May 1999

10 DATE OF REVISION OF THE TEXT

30/03/2016