PROFESSIONAL INFORMATION

SCHEDULING STATUS

S3

1 NAME OF THE MEDICINE

PEDITRACE Intravenous solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL solution contains:

Zinc chloride	521 µg
Copper chloride dihydrate	53,7 µg
Manganese chloride tetrahydrate	3,60 µg
Sodium selenite anhydrous	4,38 µg
Sodium fluoride	126 µg
Potassium iodide	1,31 µg

The active ingredients in each 1 mL solution correspond to:

Zn	3,82 µmol	(250 µg)
Cu	0,315 µmol	(20 µg)
Mn	18,2 nmol	(1 µg)
Se	25,3 nmol	(2 µg)
F	3,00 µmol	(57 µg)
I	7,88 nmol	(1 µg)

Sugar free.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intravenous solution.

A clear, colourless solution.

Osmolality: 38 mOsm/kg water

pH: 2,0

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

PEDITRACE is indicated to meet the basal requirement of trace elements during intravenous nutrition of premature and full term infants.

4.2 Posology and method of administration

Posology

The basal requirements for infants (<15 kg in weight) of the included trace elements are met by 1 mL of PEDITRACE per kg body weight per day to a maximum dose of 15 mL.

The efficacy of a daily dose of 15 mL PEDITRACE in children weighing more than 15 kg has not been established and regular monitoring of trace element plasma levels is recommended.

Up to 6 mL PEDITRACE can be added to 100 mL of a glucose solution (50 – 500 mg/mL) 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.

Method of administration

Intravenous infusion.

PEDITRACE must not be given undiluted.

For instructions on dilution of the product before administration, see section 6.6.

4.3 Contraindications

PEDITRACE is contraindicated in:

- Patients with hypersensitivity to any of the active ingredients or to the excipients in PEDITRACE (see section 6.1).
- Persons allergic to iodine.
- Wilson's disease.
- This supplement should be withheld when cholestatic liver disease is present.

4.4 Special warnings and precautions for use

The safety of PEDITRACE in patients with renal or hepatic impairment has not been established. PEDITRACE should be used with caution in patients with impaired biliary and/or renal function.

Considerable caution is required in administering PEDITRACE solution to patients with impaired biliary excretion, or compromised liver function, as copper and manganese are normally excreted via the bile. PEDITRACE should also be used with caution in patients with biochemical or clinical evidence of liver dysfunction.

Lower dosages should be given when there is impaired renal function. Such patients require careful biochemical monitoring. Selenium and zinc are mainly excreted via the urine.

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 that the requirements are being met appropriately.

PEDITRACE contains sodium and potassium

PEDITRACE contains less than 1 mmol sodium (23 mg) per 10 mL solution, i.e., essentially 'sodium-free'.

PEDITRACE contains less than 1 mmol potassium (39 mg) per 10 mL solution, i.e., essentially 'potassium-free'.

4.5 Interaction with other medicines and other forms of interaction

Concurrent administration of zinc salt with penicillamine might diminish the effect of penicillamine.

Corticosteroids in excess, increase urinary copper excretion.

4.6 Fertility, pregnancy and lactation

Pregnancy

No data available.

Breastfeeding

No data available.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

No data available.

4.8 Undesirable effects

Tabulated list of adverse reactions

System organ class	**Frequency unknown** (cannot be estimated from the available data)

Immune system disorders	Allergic reactions - may include urticaria, angioedema, cutaneous haemorrhage or purpuras, fever, arthralgia, lymphadenopathy and eosinophilia.
Endocrine disorders	Goitre, hypothyroidism, hyperthyroidism.
Vascular disorders	Superficial thrombophlebitis has been observed when glucose containing PEDITRACE was administered. However, it is not possible to deduce whether this reaction is attributable to the trace elements infusion or not.
General disorders and administration site conditions	Prolonged administration of iodine may lead to iodism.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicines regulatory authority in the country where the product is marketed.

4.9 Overdose

Chronic excessive exposure to manganese is associated with severe extrapyramidal neurological disease. Iodine excess may cause hypothyroidism.

Prolonged use of zinc may lead to copper deficiency and anaemia.

Selenium toxicity may lead to weakness, anorexia, tremors and sweating.

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

In case of a chronic overload of iron there is a risk of haemosiderosis, which can be treated by venesection in severe and rare cases.

Treatment is symptomatic and supportive. When overdosage occurs treatment should be withdrawn.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 24 Mineral substitutes, electrolytes

Pharmacotherapeutic group: Electrolytes in combination with other drugs

ATC code: B05X A31

Mechanism of action:

PEDITRACE is a sterile solution containing essential trace elements. They are generally required as co-factors for enzyme activity and thus are necessary for metabolism of the major nutrients.

5.2 Pharmacokinetic properties

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid (for pH-adjustment)

Water for injections

6.2 Incompatibilities

This medicine must not be mixed with other medicines except with those mentioned in section 6.6.

6.3 Shelf life

36 months.

The diluted solution should be used within 24 hours.

6.4 Special precautions for storage

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

For storage conditions of the diluted solution, see section 6.3.

6.5 Nature and contents of container

10 mL solution in 10 mL plastic vials in packs of 10.

6.6 Special precautions for disposal and other handling

Up to 6 mL PEDITRACE can be added to 100 mL of a glucose solution (50 – 500 mg/mL).

Only admixtures with 50 - 500 mg/mL glucose are to be used. Addition of other medicines must be avoided due to risk of precipitation.

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.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

29/24/0462

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

09 November 1995

10 DATE OF REVISION OF THE TEXT

05 March 2026