PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PEDITRACE

Intravenous solution

Sugar free.

Read all of this leaflet carefully before your child is given PEDITRACE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your child's doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What PEDITRACE is and what it is used for

PEDITRACE is used to supply trace elements during intravenous nutrition of premature and full term infants.

2. What you need to know before your child is given PEDITRACE

PEDITRACE should not be administered to your child:

- if he/she is hypersensitive (allergic) to any of the active ingredients or to the other ingredients in PEDITRACE (listed in section 6)
- if he/she is allergic to iodine
- if he/she has Wilson's disease (causing elevated copper levels)
- if he/she has cholestatic liver disease (causing a reduction or stoppage of bile flow).

Warnings and precautions

Tell your doctor or healthcare provider before your child is given the injection:

Take special care with PEDITRACE:

- if your child has liver problems
- if your child has kidney problems.

Other medicines and PEDITRACE

Always tell your child's healthcare provider if your child is taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your child's doctor if your child is taking any of the following:

- Penicillamine (used to treat Wilson's disease and other conditions).
- Corticosteroids (used to reduce inflammation in various conditions).

Pregnancy and breastfeeding

No data available.

Driving and using machines

No data available.

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’.

3. How PEDITRACE will be administered to your child

PEDITRACE will be diluted and given via slow injection into a vein (intravenous infusion).
Your doctor will decide how much PEDITRACE your child should be given.
You will not be expected to give your child PEDITRACE. It will be given to him/her by a person who is qualified to do so.

If your child receives more PEDITRACE than he/she should

Since a healthcare provider will administer PEDITRACE, he/she will control the dosage. However, in the event of overdosage your child’s doctor will manage the overdosage.

If your child’s PEDITRACE dose is forgotten

Since a healthcare provider will administer PEDITRACE, it is unlikely that the dose will be missed.

4. Possible side effects

PEDITRACE can have side effects.
Not all side effects reported for PEDITRACE are included in this leaflet. Should your child’s general health worsen or if he/she experiences any untoward effects while receiving PEDITRACE, please consult his/her healthcare provider for advice.

If any of the following happens, tell the doctor immediately:

- Allergic reactions which may include red, swollen bumps or welts on the skin, bleeding under the skin, fever, pain in the joints, swollen lymph nodes and/or skin rash.

These are very serious side effects. If your child has them, he/she may have had a serious reaction to PEDITRACE and may need urgent medical attention.

Tell your child's doctor if you notice any of the following:

Side effects with an unknown frequency:

- Swelling in the neck resulting from an enlarged thyroid gland, decreased or increased thyroid function.
- A blood clot that occurs in the veins under the skin.
- Upset stomach, thyroid problems, skin rash, headache, fever or weakness resulting from elevated iodine levels in the body.

If you notice any side effects not mentioned in this leaflet, please inform your child's doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of PEDITRACE.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or 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.

5. How to store PEDITRACE

Store all medicines out of reach of children.

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

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

The diluted solution should be used within 24 hours.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PEDITRACE contains:

The active ingredients in each 1 mL solution are:

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)

The other ingredients are hydrochloric acid (for pH-adjustment) and water for injections.

Sugar free.

What PEDITRACE looks like and contents of the pack

A clear, colourless solution.

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

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The corresponding Professional Information (PI) can be accessed at https://www.fresenius-kabi.com/za/fresenius_kabi_south_africa_products