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
2. What you need to know before your child is given PEDITRACE
3. How PEDITRACE will be administered to your child
4. Possible side effects
5. How to store PEDITRACE
6. Contents of the pack and other information

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

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

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Registration number

29/24/0462

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

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

PEDITRACE

Intraveneuse oplossing

Suikervry.

Lees die hele inligtingsblad aandagtig deur voordat PEDITRACE aan jou kind gegee word

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, raadpleeg asseblief jou kind se dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

Wat is in hierdie inligtingsblad

1. Wat is PEDITRACE en waarvoor word dit gebruik
2. Wat jy moet weet voordat PEDITRACE aan jou kind gegee word
3. Hoe PEDITRACE aan jou kind gegee word
4. Moontlike newe-effekte
5. Hoe om PEDITRACE te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat is PEDITRACE en waarvoor word dit gebruik

PEDITRACE word gebruik om spoorelemente gedurende intraveneuse voeding van premature en voltermyn babas te voorsien.

2. Wat jy moet weet voordat PEDITRACE aan jou kind gegee word

PEDITRACE moet nie aan jou kind gegee word nie:

- indien hy/sy hipersensitief (allergies) is vir die aktiewe bestanddele of enige van die ander bestanddele van PEDITRACE (gelys in afdeling 6)
- indien hy/sy allergies is vir jodium
- indien hy/sy Wilson se siekte het (wat lei tot verhoogde kopervlakke)
- indien hy/sy cholestatiese lewersiekte het (wat lei tot 'n vermindering of staking van galvloei).

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgverskaffer in voordat die inspuiting aan jou kind gegee word:

Spesiale voorsorg moet getref word met PEDITRACE:

- indien jou kind lewerprobleme het
- indien jou kind nierprobleme het.

Ander medisyne en PEDITRACE

Lig altyd jou kind se gesondheidsorgverskaffer in as jou kind enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).

Sê veral vir jou kind se dokter as jou kind een van die volgende medisyne gebruik:

- Penisillamien (gebruik vir die behandeling van Wilson se siekte en ander toestande).
- Kortikosteroïede (gebruik om inflammasie in verskeie toestande te verminder).

Swangerskap en borsvoeding

Geen data beskikbaar nie.

Bestuur en die gebruik van masjinerie

Geen data beskikbaar nie.

PEDITRACE bevat natrium en kalium

PEDITRACE bevat minder as 1 mmol natrium (23 mg) per 10 mL oplossing, dit wil sê, in wese 'natriumvry'.

PEDITRACE bevat minder as 1 mmol kalium (39 mg) per 10 mL oplossing, dit wil sê, in wese 'kaliumvry'.

3. Hoe PEDITRACE aan jou kind gegee word

PEDITRACE word verdun en stadig in 'n aar ingespuit (intraveneuse infusie).

Jou dokter sal besluit hoeveel PEDITRACE jou kind gegee moet word.

Daar sal nie van jou verwag word om PEDITRACE aan jou kind toe te dien nie. Dit sal aan hom/haar toegedien word deur 'n persoon wat gekwalifiseer is om dit te doen.

Indien jou kind meer PEDITRACE ontvang het as wat hy/sy moes

Aangesien 'n gesondheidsorgverskaffer PEDITRACE sal toedien, sal hy/sy die dosis beheer.

In geval van oordosering sal jou kind se dokter egter die oordosering behandel.

Indien jou kind se PEDITRACE dosis oorgeslaan is

Aangesien 'n gesondheidsorgverskaffer PEDITRACE sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.

4. Moontlike newe-effekte

PEDITRACE kan newe-effekte hê.

Nie alle newe-effekte wat vir PEDITRACE aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou kind se algemene gesondheid verswak of as jou kind enige ongunstige effekte ondervind terwyl hy/sy PEDITRACE ontvang, raadpleeg asseblief sy/haar gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, lig die dokter dadelik in:

- Allergiese reaksies - mag rooi, geswolle knoppe of galbulte op die vel, bloeding onder die vel, koors, gewrigspyn, geswolle limfkliere en/of veluitslag insluit.

Hierdie newe-effekte is almal baie ernstig. Indien jou kind hierdie simptome het, het hy/sy moontlik 'n ernstige reaksie op PEDITRACE gehad en benodig hy/sy dringend mediese aandag.

Lig jou kind se dokter in indien jy enige van die volgende waarneem:

Newe-effekte met 'n onbekende frekwensie:

- Swelling in die nek as gevolg van 'n vergrote skildklier, verminderde of verhoogde skildklierwerking.
- 'n Bloedklont wat in die are onder die vel voorkom.
- Omgekrapte maag, skildklierprobleme, veluitslag, hoofpyn, koors of swakheid as gevolg van verhoogde jodiumvlakke in die liggaam.

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingsblad vermeld word nie, lig asseblief jou kind se dokter of apteker in.

Aanmelding van newe-effekte

Indien jy newe-effekte ervaar, bespreek dit met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org) op die SAHPRA webwerf. Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van PEDITRACE te verskaf.

Pasiënte word versoek om enige vermoedelike ongunstige newe-effekte van geneesmiddels aan hulle gesondheidsorgverskaffer of die Houer van die Registrasiesertifikaat by die volgende e-posadres aan te meld: safety.fksa@fresenius-kabi.com en aan die betrokke medisyne se regulatoriese owerheid in die land waar die produk bemark word.

5. Hoe om PEDITRACE te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar by of onder 25 °C. Moenie vries nie. Beskerm teen lig.

Moenie in 'n badkamer bêre nie.

Moenie na die vervaldatum wat op die etiket gedruk is, gebruik nie.

Die verdunde oplossing moet binne 24 uur gebruik word.

Neem alle ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting

Wat PEDITRACE bevat:

Die aktiewe bestanddele in elke 1 mL oplossing is:

Sinkchloried	521 µg
Koperchloried-dihidraat	53,7 µg
Mangaanchloried tetrahidraat	3,60 µg
Natriumseleniet anhidries	4,38 µg
Natriumfluoried	126 µg
Kaliumjodied	1,31 µg

Die aktiewe bestanddele in elke 1 mL oplossing kom ooreen met:

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)

Die ander bestanddele is soutsuur (vir pH-aanpassing) en water vir inspuiting.

Suikervry.

Hoe PEDITRACE lyk en inhoud van die pakkie

'n Helder, kleurlose oplossing.

10 mL oplossing in 10 mL plastiese flessies in pakke van 10.

Houer van die Registrasiesertifikaat

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Hierdie inligtingsblad is voorheen hersien op

05 Maart 2026

Registrasienommer

29/24/0462

Toegang tot die ooreenstemmende Professionele Inligting

Die ooreenstemmende Professionele Inligting (PI) kan verkry word by https://www.fresenius-kabi.com/za/fresenius_kabi_south_africa_products