

Peditrace

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
 - If you have any further questions, ask your doctor or nurse.
 - If you get any side effects, talk to your doctor or nurse.
- This includes any possible side effects not listed in this leaflet. See section 4.



What is in this leaflet:

1. What Peditrace is and what it is used for
2. What you need to know before you use Peditrace
3. How to use Peditrace
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 a mixture of trace elements in amounts normally absorbed from the oral diet. Peditrace is indicated in infants and children needing intravenous nutrition to supply the basal requirements of trace elements.

What you need to know before you use Peditrace

Do not use Peditrace

If you have Wilson's Disease.

Warnings and precautions

Talk to your doctor or nurse before using Peditrace

- 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

3. How to use Peditrace

Peditrace must be given diluted.

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.

Additions should be made aseptically.

Additions

Up to 6 ml Peditrace can be added to 100 ml Vaminolact, Vamin 9 Electrolyte Free, 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.

STABILITY

When additions are made to an infusion solution, the infusion should be completed within 24 hours from preparation to prevent microbiological contamination. The leftover contents of opened bottles/vials/ampoules should be discarded and not kept for later use.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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 is 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.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system listed below.

By reporting side effects, you can help provide more information on the safety of this medicine. To report any side effect(s):

Saudi Arabia:

The National Pharmacovigilance Centre (NPC):

- SFDA Call Center: 19999
- E-mail: npc.drug@sfd.gov.sa
- Website: <https://ade.sfd.gov.sa/>

UAE:

Pharmacovigilance & Medical Device section:

- P.O.Box: 1853
- Tel: 80011111
- E-mail: pv@mohap.gov.ae
- Drug Department
- Ministry of Health & Prevention – Dubai- UAE

Other GCC states:

Please contact the relevant competent authority

How to store Peditrace

Do not store above 25°C. Do not freeze.

5. Contents of the pack and other information

Vial for injection, polypropylene plastic.

Pack size: 10 x 10 ml

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder:

Fresenius Kabi AB
SE-75174 Uppsala
Sweden

Manufacturer:

HP Halden Pharma AS
Svinesundsveien 80
1788 Halden
Norway

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers Union of Arab Pharmacists

This leaflet was last revised in December 2008

01-58-16-024B