

PACKAGE LEAFLET: INFORMATION FOR THE USER

Peditrace® concentrate for solution for infusion

Read all of this leaflet carefully before this medicine is given.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you notice any side effects, including those not listed in this leaflet, please tell your doctor, pharmacist or nurse.

What is in this leaflet

1. What Peditrace is and what it is used for
2. What you need to know before your child receives Peditrace
3. How your child will be given 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 especially designed for babies and children. It provides trace elements to your child when they cannot eat normally.

It is usually used as part of a balanced intravenous diet, together with proteins, fats, carbohydrates, salts and vitamins.

2. What you need to know before your child receives Peditrace®

Your child should not receive Peditrace :

- if they are allergic to Peditrace or any of the other ingredients of this medicine (listed in section 6). **If your child develops a rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), please inform their doctor, pharmacist or nurse.**
- If they suffer from Wilson's Disease (**an inherited disorder where there is excessive amount of copper in the body's tissue**)

Peditrace must be diluted before use. It will be added to another solution before it is given to your child. Your doctor or nurse will make sure it is prepared correctly.

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before Peditrace is given to your child if they:

- have liver or kidney problems

Your doctor may want to do regular blood tests to check your child's condition.

Other medicines and Peditrace

Tell your doctor or pharmacist if your child is taking, have recently taken or might take any other medicines.

3. How your child will be given Peditrace®

Your child will receive this medicine by infusion (IV drip). Peditrace will be added to an amino acid or glucose solution before it is given to your child. Your doctor will decide on the correct dose for him/her to receive.

Dosage

For infants and children up to 15 kg bodyweight

The usual daily dose of Peditrace is 1 ml for every kg of body weight. The maximum dose is 15 ml/day.

For children of 15-40 kg bodyweight

The daily dose is 15 ml/day.

Another trace element solution called Additrace® is more suitable for children weighing over 40 kilograms.

If your child receives more Peditrace® than they should

It is very unlikely that your child will receive more infusion than he/she should as the doctor or nurse will monitor him/her during the treatment. However if you think that your child has received too much Peditrace, inform the doctor or nurse immediately. Symptoms of overdose include: headache, nausea, vomiting and drowsiness.

If you have any further questions on the use of this product, ask your doctor or pharmacist

4. Possible side effects

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

No known side effects have been reported with the use of Peditrace.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist 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.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Peditrace®

Keep this medicine out of the sight and reach of children.

Your doctor or hospital pharmacist are responsible for the correct storage, use and disposal of Peditrace infusion. Do not store above 25°C. Do not freeze. Keep container in the outer carton. This product must not be used after the expiry date which is stated on the carton and the vial labels. The expiry date refers to the last day of that month.

Do not use this medicine if it is cloudy or contains particles. Do not throw away any medicine via wastewater. Any medicine remaining after treatment should be disposed of via approved hospital procedures. These measures will help protect the environment.

6. Contents of the pack and other information

What Peditrace contain

The active substances in 1 ml are:

Each 1 ml contains:

Zinc Chloride	521 micrograms
Copper Chloride 2H ₂ O	53.7 micrograms
Manganese Chloride 4H ₂ O	3.60 micrograms
Sodium Selenite Anhydrous	4.38 micrograms
Sodium Fluoride	126 micrograms
Potassium Iodide	1.31 micrograms

The ingredients in 1 ml correspond to;

Zinc	250 micrograms	3.82 micromol
Copper	20 micrograms	0.315 micromol
Manganese	1 micrograms	18.2 nanomol
Selenium	2 micrograms	25.3 nanomol
Fluoride	57 micrograms	3.0 micromol
Iodide	1 micrograms	7.88 nanomol

The other ingredients are Hydrochloric acid and Water for injections.

What Peditrace® looks like and contents of the pack

Peditrace is a sterile clear, colourless solution containing trace elements. Each plastic vial contains 10 ml of solution. Each carton contains 10 vials.

Marketing authorisation holder

MAH for UK

Fresenius Kabi Limited
Cestrian Court
Eastgate Way
Manor Park
Runcorn
Cheshire
WA7 1NT
UK

MAH for IRL

Fresenius Kabi Deutschland GmbH Else-
Kröner-Straße 1,
61352 Bad Homburg v.d.Höhe
Germany

Manufacturer

HP Halden Pharma AS
Svinesundsveien 80
1788 Halden
Norway

This leaflet was revised in March 2024.