Peditrace™

Concentrate for solution for infusion

FRESENIUS KABI

Trace element additive solution for pediatric patients on total parenteral nutrition.

COMPOSITION

1 ml contains:

Zinc chloride	521 µg
Copper chloride $2H_20$	53.7 µg
Manganese chloride $4H_20$	3.60 µg
Sodium selenite anhydrous	4.38 µg
Sodium fluoride	126 µg
Potassium iodide	1.31 µg

Hydrochloric acid to pH 2
Water for injections to 1 ml

PROPERTIES

Sterile solution containing trace elements for addition to amino acid solution or glucose solution (see compatibility) in the parenteral nutrition of premature and fullterm infants and children.

The content of trace elements in 1 ml Peditrace is given below:

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

Osmolality: 38 mosm/kg water. pH 2.0

INDICATION

Peditrace is intended to meet the basal requirement of trace elements during intravenous nutrition of infants and children.

CONTRAINDICATION

Wilson's disease.

PRECAUTIONS

Peditrace should be used with caution when the excretion in bile is reduced, particularly in cholestatic liver disease, or when the urinary excretion is markedly reduced. Such patients require careful biochemical monitoring.

Copper and manganese are normally excreted via the bile, whereas selenium and zinc (especially in patients receiving intravenous nutrition) are mainly excreted via the urine. If the treatment is continued for more than 4 weeks, control of manganese level is required.

DOSAGE AND ADMINISTRATION

Must not be given undiluted.

The basal requirements for infants and children 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.

A daily dose of 15 ml Peditrace should also meet the basic needs of trace elements in children weighing more then 15 kg. Patients with increased losses or requiring prolonged intravenous nutrition should be monitored biochemically to confirm that requirements are being appropriately met.

Peditrace can be added to either an amino acid solution or glucose solution and given during a minimum infusion period of 8 hours.

Some paediatirc admixtures with Peditrace are tested and found compatible (see page 4).

The infusion should be given at a very slow rate and is best done with an appropriate pump or an automatic drop rate counter.

COMPATIBILITY

Up to 6 ml Peditrace can be added to 100 ml Vaminolact™, Vamin™ 14 EF or glucose solution (50 mg/ml -500 mg/ml). When Peditrace is administered as admixture, see table page 4.

Only admixtures in which compatibility has been documented are to be used.

The addition of Peditrace must be done aseptically. To minimize the risk of infection the infusate should be used within 24 hours.

Addition of other drugs must be avoided due to the risk of incompatibilities.

Black

STORAGE

Do not store above 30 °C. Do not freeze.

Admixtures compatibility with Peditrace

Infusion solution	Per litre admixture	Added amounts of electrolytes (up to mmol/l)				
		NaCl	KCl	$CaCl_2$	$MgSO_4$	KH_2PO_4
Peditrace Vaminolact Glucose	up to 13.3 ml 287 ml 66.7 g	65.3	40.0	25.3	6.0	6.7
Peditrace Vaminolact Glucose	up to 13.3 ml 400 ml 100 g	32.7	20.0	12.7	3.3	7.3
Peditrace Vaminolact Glucose	up to 6.7 ml 400 ml 100 g	65.3	40.0	25.3	6.0	6.7

The admixtures must be compounded using strict aseptic techniques and in aseptic working conditions to prevent bacterial contamination.

These admixtures will remain stable when stored for up to 6 days at 5 ± 3 ^{O}C followed by 24 hours at 25 ± 5 ^{O}C.

PACKAGE

10 ml vials (polypropylene plastic) packed in boxes of 10.

MANUFACTURER:

HP Halden Pharma AS,Svinesundsveien 80, Halden, 1788, Norway for Fresenius Kabi AB, Uppsala, Sweden.

PRODUCT REGISTRATION HOLDER/IMPORTER:

Fresenius Kabi Malaysia Sdn Bhd
3-1 & 3-2, Axis Technology Centre,
Lot 13 Jalan 51A/225, 46100 Petaling Jaya, Selangor.

Zuellig Pharma (B) Sdn Bhd,
Unit 5 1st Floor, Spg 607,
Jln Gadong Kg Beribi,
Bandar Seri Begawan BE1118, Brunei Darussalam.

DATE OF REVISION:

Apr 2024