

SmPC

Country :	Lebanon
Date of approval :	07.07.1998
Procedure:	National

SUMMARY OF PRODUCT CHARACTERISTICS

1- NAME

PEDIATRIC TRACE ELEMENTS CHILD AND BABY, solution for infusion in vial.

2- QUALITATIVE AND QUANTITATIVE COMPOSITION

Ferrous gluconate dihydrate.....	431.71 mg
Copper gluconate	214.46 mg
Manganese gluconate dihydrate	87.60 mg
Zinc gluconate trihydrate	779.63 mg
Sodium fluoride	110.53 mg
Cobalt gluconate	114.34 mg
Sodium selenite.....	10.95 mg
Sodium iodide.....	5.91 mg
Chromium chloride hexahydrate	10.25 mg
Ammonium molybdate quadrihydrate.....	9.20 mg
Water for injection	qsp 1000 ml

Iron:	0.89 mmol/l
Copper:.....	0.47 mmol/l
Manganese:.....	0.18 mmol/l
Zinc:.....	1.53 mmol/l
Fluorine:	2.63 mmol/l
Cobalt:	0.25 mmol/l
Iodine:.....	0.04 mmol/l
Selenium:	0.06 mmol/l
Molybdenum:...	0.05 mmol/l
Ammonia:	0.043 mmol/l
Gluconate:	6.64 mmol/l
Chloride:	0.12 mmol/l
Sodium:	2.73 mmol/l
Chromium:.....	0.04 mmol/l

Osmolarity: ... 15.6 mOsm/l

3- PHARMACEUTICAL FORM

Solution for injection for infusion.

4- CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment for deficiencies by supplements of trace elements during prolonged parenteral nutrition in children and infants.

4.2 Posology and method of administration

1 mL/kg/day in a parenteral nutrition mixture.

Compatibility and stability in the case of each nutritional mixture should be verified prior to use.

4.3 Contraindication

4.4 Special warnings and special precautions for use

Monitoring of serum levels of copper, zinc, selenium and iron.

4.5 Interactions with other medicinal products and other forms of interaction

4.6 Pregnancy and lactation

4.7 Effects on ability to drive and use machinery

4.8 Adverse effects

No clinical signs of intolerance have been observed to date.

4.9 Overdose

5- PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Combination of 10 trace elements (Iron, Copper, Manganese, Zinc, Fluorine, Cobalt, Iodine, Chromium, Selenium, Molybdenum).

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6- PHARMACEUTICAL DATA

6.1 Incompatibilities

6.2 Shelf life

2 years.

6.3 Special precautions for storage

Store the vial in the outer packaging, away from light.

6.4 Type and capacity of container

6.5 Method of use, instructions for handling

Before use, verify that the solution is homogenous and that the vial is free of cracks or chips. Inspect the solution visually before use.

Only use a transparent, particle-free solution.

After use, any opened vial must be discarded.