Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Additrace, concentrate for solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains 10ml of concentrate.
Each 1 ml of concentrate contains:

Ferric chloride, 6H2O Ph. Eur.	540	microgram
Zinc chloride Ph. Eur	1.36	mg
Manganese chloride $4H_2O$ USP	99.0	microgram
Copper chloride $2H_2O$ USP	340	microgram
Chromic chloride $6H_2O$ USP	5.33	microgram
Sodium Selenite anhydrous	6.9	microgram
Sodium molybdate, $2H_2O$ Ph. Eur.	4.85	microgram
Sodium fluoride BP	210	microgram
Potassium iodide Ph. Eur	16.6	microgram

One 10ml ampoule of Additrace contains:

Fe^{3+}	20	micromol
Zn^{2+}	100	micromol
Mn^{2+}	5	micromol
Cu^{2+}	20	micromol
Cr^{3+}	0.2	micromol
Se^{4+}	0.4	micromol
Mo^{6+}	0.2	micromol
F^-	50	micromol
I^-	1	micromol

Less than 1 mmol of both potassium and sodium.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion

Sterile, clear, almost colourless solution for addition to amino acid solutions

- Osmolality: approx. 3100 mosm/kg water
- pH: 2.3 – 2.8

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A source of electrolytes and trace elements as an integral part of a complete intravenous nutritional regimen, for adults and children over 40 kg.

4.2 Posology and method of administration

Posology
Adults
One 10ml ampoule of Additraceis added to one of the following Vamin solutions:

Vamin 9 Glucose, Vamin 14, Vamin 14 Electrolyte-Free, Vamin 18 Electrolyte-Free, Glucose Intravenous Infusion 5-50%

The mixture should be infused at an appropriate rate for the amino acid solution.

Paediatric Population
Additrace is contradindicated in infants and children under 40kg body weight.
The electrolyte solution Pedictraceshould be used.

Method of administration
Intravenous infusion after dilution.
Additracemust not be given undiluted. For instructions on dilution of the medicinal product before administration, see section 6.6.
Dosage is dependent on age, weight and any degree of deficiency of the patient and must be decided on an individual basis.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Care should be taken in the administration of Additrace to patients with impaired liver function (especially cholestasis). Manganese toxicity is more likely to occur in patients with impaired liver function and cholestasis as manganese is almost entirely dependent on the biliary route for excretion. Manganese blood levels and liver function should be monitored regularly (monthly) in such patients. Additrace should be stopped if manganese levels rise to the potentially toxic range. (Please refer to appropriate reference ranges for the testing laboratory.)

Additrace should be used with caution in patients with impaired renal function when the excretion of some trace elements (zinc, selenium, fluoride, chromium and molybdenum) may be significantly decreased.

No other additions should be made to solutions containing Additraceunless compatibility is known.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

No hazard is expected if used in pregnancy at the recommended dosage. No animal studies have been performed. There are, however, published reports on safe and successful use of trace elements as part of a Total Parenteral Nutrition (TPN) regimen during pregnancy in the human.

Foetal bradycardia may occur following administration of parenteral irons. It is usually transient and a consequence of a hypersensitivity reaction in the mother. The unborn baby should be carefully monitored during intravenous administration of parenteral irons to pregnant women.

4.7 Effects on ability to drive and use machines

Additrace has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

There have been no reported undesirable effects observed during the administration of Additrace.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

In general, overdosage with Additrace is extremely unlikely as the quantity of trace elements per ampoule lies well below known toxic levels of administration.

Chronic overdosage may very rarely occur secondary to an unsuspected idiosyncratic deficiency in metabolism or excretion of a trace element. In this case, signs, such nail dystrophy and insidious onset of symptoms secondary to haematological changes or tissue deposition, may be observed. Diagnosis would be confirmed by biochemical or haematological tests and treatment with Additrace should be withdrawn.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Additrace is formulated to supply trace elements for intravenous infusion.

Pharmacotherapeutic group: concentrate for solution for infusion.
ATC code: B05X A31

5.2 Pharmacokinetic properties

Additrace is a formulation of trace elements without interest for pharmacokinetic studies.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xylitol
Hydrochloric Acid 1M (for pH adjustment only)
Water for Injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

Unopened: 3 years

After dilution: The addition of Additrace should be performed aseptically immediately before the start of the infusion and should be used within 24 hours. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2- 8°C, unless mixing has taken place in controlled and validated aseptic conditions. See section 4.2.

6.4 Special precautions for storage

Store below 25˚C. Do not freeze.
Store ampoules in the outer carton in order to protect from light.
For storage conditions after dilution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Clear glass ampoule (Ph. Eur., Type I) and Polypropylene ampoule (Ph. Eur. monograph on polypropylene for containers for preparations for parenteral use) containing 10ml of concentrate.

Pack size:	Glass ampoule	10 × 10ml
	Polypropylene ampoule	20 × 10ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Additrace must not be given undiluted. The addition of Additraceshould be performed aseptically, immediately before the start of infusion. See section 6.3 for in use shelf life.

Data on compatibility of Additracewith various admixtures is available upon request.
The following admixtures are compatible with Additrace and should be used with 24 hours of mixing:

Admixture	Storage conditions
Vamin 9 Glucose	25° ± 3° C
Vamin 14	25° ± 3° C
Vamin 14 Electrolyte-Free	25° ± 3° C
Vamin 18 Electrolyte-Free	25° ± 3° C
Glucose Intravenous Infusion 5- 50%	25° ± 3° C

Do not use if the Additrace solution is cloudy, contains sediment.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352
Germany

8 MARKETING AUTHORISATION NUMBER

PA2059/023/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:16th May 1988

Date of last renewal: 16th May 2008

10 DATE OF REVISION OF THE TEXT

March 2020