Prescribing information

For ROI Healthcare Professionals only.

Additrace® N Concentrate for solution for infusion. Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Active ingredients:** Each 10ml ampoule of Additrace N contains: Chromic chloride hexahydrate 53.3 microgram, Copper chloride dihydrate 1.02 milligram, Ferric chloride hexahydrate 5.40 milligram, Manganese chloride tetrahydrate 198 microgram, Potassium iodide 166 microgram, Sodium fluoride 2.10 milligram, Sodium molybdate dihydrate 48.5 microgram, Sodium selenite anhydrous 173 microgram, Zinc chloride 10.5 milligram. **Indications:** To meet basal to moderately increased requirements of trace elements in intravenous nutrition. **Dosage and administration:** Additrace N must not be given undiluted; only add to medicinal or nutritional solutions for which compatibility has been documented. Recommended daily dosage for adults with basal to moderately increased requirements: 1 ampoule (10ml). Additrace N is not recommended for use in children weighing under 40kg body weight; Peditrace® should be used. Dosage is dependent on age, weight and any degree of deficiency of the patient and must be decided on an individual basis. **Contraindications:** Hypersensitivity to the active substances or any of the excipients, conditions with total biliary obstruction, Wilson's disease. **Special warnings and precautions for use:** Use with caution in patients with impaired biliary and/or renal function in whom the excretion of trace elements (zinc, selenium, fluoride, chromium and molybdenum) may be significantly decreased, and in patients with biochemical or clinical evidence of liver dysfunction (especially cholestasis). Check manganese blood levels if treatment continued for more than 4 weeks. Stop Additrace N if manganese levels rise to the potentially toxic range (refer to appropriate reference ranges of the testing laboratory). Carefully monitor the unborn baby during intravenous administration of parenteral irons to pregnant women; foetal bradycardia can occur. **Undesirable effects:** No adverse effects related to the trace elements in Additrace N have been reported. Other adverse reactions can occur, see SmPC for details. **Legal Category:** POM **Marketing Authorisation Holder:** Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.h. 61352, Germany. Marketing Authorisation Number: PA 2059/023/002 **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** December 2020 API/AdditraceN-01

Date of preparation: November 2023; IE-3CB-2300009

FRESENIUS KABI