Prescribing information available here for the Fresenius Kabi parenteral nutrition micronutrient products, please scroll.

Solivito® N Powder for Concentrate for Solution for Infusion (thiamine, riboflavine, nicotinamide, pyridoxine, sodium pantothenate, sodium ascorbate, biotin, folic acid, cyanocobalamin)

Active ingredients: Thiamine Mononitrate 3.1mg, Sodium Riboflavine Phosphate 4.9mg, Nicotinamide 40mg, Pyridoxine Hydrochloride 4.9mg, Sodium Pantothenate 16.5mg, Sodium Ascorbate 113mg, Biotin 60 micrograms, Folic acid 0.4mg, Cyanocobalamin 5 micrograms. Excipients with known effect: methyl parahydroxybenzoate 0.5mg per vial. **Indications:** A supplement in intravenous nutrition to provide the daily requirements of water-soluble vitamins in adults and children. **Dosage and administration:** For intravenous infusion after dilution in a compatible solution (refer to SmPC). One vial should be infused over a minimum of two to three hours in patients with normal renal function. All additions should be made aseptically. Adults and children 10kg or more: one vial daily. Solivito N may be added to parenteral nutrition admixtures provided compatibility and stability have been confirmed. Infants and children under 10kg: 1/10 the contents of one vial per kg body weight/day. **Contraindications:** Hypersensitivity to any of the active substances or excipients. Precautions for use: Biotin may interfere with laboratory tests that are based on a biotin/streptavidin interaction, leading to either falsely decreased or falsely increased test results, depending on the assay. Possible biotin interference has to be taken into consideration when interpreting results of laboratory tests, especially if a lack of coherence with the clinical presentation is observed. Laboratory personnel should be consulted when ordering laboratory tests in patients taking biotin. **Interactions:** Pyridoxine (Vitamin B6) can reduce the effect of levodopa. Some of the optic neuropathies appear to respond to massive doses of hydroxocobalamin and have been claimed to be adversely affected by administration of cyanocobalamin. Folic acid may lower the serum concentration of phenytoin and obscure pernicious anaemia. **Undesirable effects:** Anaphylactic reaction (risk level cannot be estimated from the available data). Other adverse reactions can occur, see SmPC for details. **Legal category:** POM. **Marketing authorisation number:** PL 08828/0116. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package size and cost:** 10 vials - £19.70. **Further information:** Prescribers should consult the summary of product characteristics in relation to other adverse reactions. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk.** Adverse events should also be reported to Fresenius Kabi Limited. **Date of preparation:** May 2020.

Vitlipid® N Adult Concentrate for Emulsion for Infusion (ergocalciferol, phytomenadione, retinol palmitate, dl-alpha-tocopherol)

Active ingredients: In 10ml - Retinol Palmitate corresponding to retinol 990mcg (3,300IU), Ergocalciferol 5mcg (200IU), dl-alpha-tocopherol 9.1mg (10 IU), Phytomenadione 150mcg. **Indications:** In adults and children from 11 years of age as

a supplement in intravenous nutrition in order to meet the daily requirements of the fat-soluble vitamins A1, D2, E and K1. **Dosage and administration:** Recommended daily dosage for adults, the elderly and children over 11 years of age: One ampoule (10ml) Vitlipid N Adult is added to 500ml of Intralipid 10% or 20%. **Contraindications:** Hypersensitivity to egg, soya, or peanut protein or to any of the active substances or excipients. **Special warnings and precautions for use:** Contains soya-bean oil and egg phospholipids which may rarely cause allergic reaction. Cross allergic reaction has been observed between soya-bean and peanut. Must not be administered undiluted. The addition of the formulation to infusion solutions should be made aseptically and the solution used within 24 hours of preparation. **Undesirable effects:** None reported. Adverse reactions can occur, see SmPC for details. **Legal category:** POM. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. **Marketing authorisation number:** PL 8828/0124. **Package size and cost:** 10 x 10ml - £19.70. **Further information:** See the SmPC for further details. **Adverse events should be reported.** Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk.** Adverse events should also be reported to Fresenius Kabi Limited. **Date of revision:** June 2021.

Vitlipid® N Infant Concentrate for Emulsion for Infusion (ergocalciferol, phytomenadione, retinol palmitate, dl-alpha-tocopherol)

Active ingredients: One ml contains – Retinol palmitate 69mcg corresponding to retinol (230 IU), Ergocalciferol 1.0mcg (40 IU), dl-alpha-tocopherol 0.64mg (0.7 IU), Phytomenadione 20mcg. **Indications:** Vitlipid N Infant is indicated in infants and children up to 11 years of age as a supplement in intravenous nutrition to meet the daily requirements of the fat-soluble vitamins A1, D2, E and K1. **Dosage and administration:** For intravenous infusion after dilution. Infants and children under 11 years of age: 4ml/kg bodyweight/day for pre-term and low birth weight infants up to 2.5kg bodyweight. 10ml/day for all infants and children weighing more than 2.5kg up to 11 years of age. **Contraindications:** Should not be given undiluted. Hypersensitivity to egg, soya, peanut protein or any of the active substances or excipients. **Special warnings and precautions for use:** Contains soya-bean oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. The addition of the formulation to the infusion solutions should be made aseptically and the solution used within 24 hours of preparation. **Undesirable effects:** None reported. Adverse reactions can occur, see SmPC for details. **Legal category:** POM **Marketing Authorisation Holder**: Fresenius Kabi Ltd, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. **Marketing authorisation number:** PL 08828/0125. **Package size and cost:** 10 x 10ml - £19.70. **Further information:** See the SmPC for further details. **Adverse events should be reported.** Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk** Adverse events should also be reported to Fresenius Kabi Limited. **Date of revision:** September 2024.

Sodium Glycerophosphate 21.6% concentrate for solution for infusion (organic phosphate solution for parenteral nutrition)

Active Ingredients: 20ml contains 4320mg of Sodium glycerophosphate pentahydrate, which corresponds to 20mmol Phosphate and 40mmol Sodium. **Indications**: To be used in adults as a supplement in intravenous parenteral nutrition to meet the requirements of phosphate. **Dosage and administration**: To meet the recommended daily dose of phosphate (10-20mmol) during intravenous nutrition, 10-20ml of Sodium Glycerophosphate 21.6% can be added to the infusion solution or to the admixture for which compatibility has been shown. **Contraindications**: Dehydration, hypernatraemia, hyperphosphataemia, severe renal insufficiency, shock, hypersensitivity to the active substances or excipients. **Special warnings and precautions for use**: Use with caution in patients with impaired renal function. Phosphate status should be monitored regularly. Do not give undiluted. **Undesirable effects**: None reported. Legal Category: POM. **Marketing Authorisation Holder:** Fresenius Kabi Ltd, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. **Marketing Authorisation Number**: PL 08828/0147. **Package size and cost**: 10 x 20ml £50.70. **Further information:** See SmPC for further details. **Adverse events should be reported**. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk**. Adverse events should also be reported to Fresenius Kabi Limited. **Date of revision**: April 2020.

Addaven® Concentrate for Solution for Infusion (chromium, copper, iron, manganese, iodine, fluoride, molybdenum, selenium, zinc)

Active ingredients: One ampoule of 10ml Addaven 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 173 microgram, Zinc chloride 10.5 milligram. **Indications:** To meet basal to moderately increased requirements of trace elements in intravenous nutrition. **Dosage and administration:** Addaven must not be given undiluted. Recommended daily dosage in adults with basal to moderately increased requirements is 10ml (one ampoule). Addaven is not recommended for use in children under 40kg of body weight. For children weighing less than 40kg, the trace element solution Peditrace® should be used. **Contraindications:** Hypersensitivity to the active substances or excipients. **Special warnings and precautions for use:** Caution in patients with impaired biliary and/or renal function due to a decrease in excretion, which may lead to accumulation. Caution in patients with biochemical or clinical evidence of liver dysfunction (especially cholestasis). If the treatment exceeds 4 weeks, checking of manganese levels in blood is required. Individual requirements of trace elements should be considered and separate supplementation may be required. **Undesirable effects:** None known. **Legal Category:** POM. **Marketing Authorisation Holder:** Fresenius Kabi Ltd, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK Marketing Authorisation Number: PL 08828/0275. **Package size and cost:** 20 x 10ml ampoules £55 **Further information:**

See SmPC for details. **Adverse events should be reported.** Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk**. Adverse events should also be reported to Fresenius Kabi Limited. **Date of revision:** May 2019.

Peditrace® concentrate for solution for infusion (zinc, copper, manganese selenium, fluoride, iodide)

Active ingredients: 1ml of Peditrace contains: zinc chloride 521 microgram, copper chloride dihydrate 53.7 microgram, manganese chloride tetrahydrate 3.60 microgram, sodium selenite anhydrous 4.38 microgram, sodium fluoride 126 microgram, potassium iodide 1.31 microgram. **Indications:** An integral part of the complete intravenous nutrition of infants and children. It is intended to meet basal requirements for trace elements and should be used in conjunction with amino acid or glucose solutions or other paediatric admixtures. **Dosage and administration:** Peditrace should not be given undiluted. Infants and children (weighing 15 kg or less): Basal requirements of the included trace elements are covered by 1 ml Peditrace per kg body weight per day to a maximum daily dose of 15 ml. Children (weighing 15 kg or more): A daily dose of 15 ml Peditrace should meet basal trace element requirements. However, for patients weighing more than 40 kg the adult preparation Additrace should be used. Peditrace administration should not be started until kidney function is established – usually during the second day of life. The infusion should be given at a very slow rate (minimum infusion period is 8 hours). Requirements can vary in different clinical conditions; trace elements may have to be added as appropriate in the individual patient. Biochemical monitoring in patients likely to lose higher than average amounts of trace elements or those requiring prolonged intravenous nutrition. **Contraindications:** Hypersensitivity to the active substance(s) or excipients, Wilson's disease. **Special warnings and precautions for use:** Administration should be carried out under specialist surveillance, especially in patients with pre-existing imbalances, in renal failure or in hepatic disease. Peditrace should be used with caution in conditions where excretion in the bile is reduced, particularly when cholestatic liver disease is present and/or when urinary excretion is markedly reduced. Patients with such conditions require careful biochemical monitoring as the excretion of trace elements may also be significantly decreased. Patients requiring long term TPN (longer than one month) should have baseline whole blood or serum manganese level within or below normal range and normal liver function before receiving Peditrace. Manganese levels and liver function should be monitored regularly (monthly) while the patient is maintained on Peditrace. Peditrace should be stopped if manganese levels rise into the potentially toxic range or if cholestasis develops. **Undesirable effects:** Impaired renal or hepatic excretion may lead to chronic overdose of one or more trace elements. Chronic overdose of manganese recorded as causing Parkinsonism and psychosis. Chronic overdosage may very rarely occur secondary to unsuspected idiosyncratic deficiency in metabolism or excretion for a specific trace element; confirm diagnosis and withdraw Peditrace. See SmPC in relation to adverse reactions. **Legal Category:** POM. **Marketing Authorisation Holder:** Fresenius Kabi Ltd, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. **Marketing Authorisation Number:** PL 08828/0115.

Package size and cost: 10 x 10ml vials £35.30. **Further information:** See SmPC for details. **Adverse events should be reported.** Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk** Adverse events should also be reported to Fresenius Kabi Limited. **Date of revision:** September 2024.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk Adverse events should also be reported to Fresenius Kabi Limited.
Email: Pharmacovigilance.GB@fresenius-kabi.com