

Prescribing information

For ROI Healthcare Professionals only.

SOLIVITO® N powder for concentrate for solution for infusion. Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Active ingredients:** One 10 ml vial contains Thiamine nitrate 3.1 mg, Riboflavin Sodium Phosphate 4.9 mg, Nicotinamide 40 mg, Pyridoxine Hydrochloride 4.9 mg, Sodium Pantothenate 16.5 mg, Sodium Ascorbate 113 mg, Biotin 60 micrograms, Folic acid 0.4 mg, Cyanocobalamin 5 micrograms. **Excipients:** 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. **Adults, elderly and children 10kg or more:** one vial daily. **Infants and children under 10kg:** 1/10 the contents

of one vial per kg body weight/day. Solivito N may be added to parenteral admixtures containing carbohydrates, lipids, amino acids, electrolytes and trace elements provided that compatibility and stability have been confirmed. **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. Care in the administration of cyanocobalamin with some of the optic neuropathies. If Solivito N is diluted with water based solutions the admixture should be protected from light. Folic acid may obscure

pernicious anaemia. Methyl parahydroxybenzoate may cause allergic reactions (possibly delayed), including bronchospasm. **Interactions:** Pyridoxine (Vitamin B6) can reduce the effect of levodopa. Folic acid may lower the serum concentration of phenytoin. **Undesirable effects:** Allergic reactions, 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:** PA 2059/064/001. **Marketing Authorisation Holder:** Fresenius Kabi Deutschland GmbH, Else-Kroener Straße 1, Bad Homburg 61352, v.d.Höhe, Germany. **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:** November 2020 API/Solivito-01