NEW ZEALAND DATA SHEET

1. PRODUCT NAME

SOLUVIT® N (Injection, powder)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One vial contains:

Active ingredients	Quantity	1 ml of reconstituted Soluvit N contains
Thiamine nitrate	3.1 mg	0.31 mg
Sodium riboflavine phosphate (*corresponding to Vitamin B_2 3.6 mg*)	4.9 mg	0.49mg
Nicotinamide	40 mg	4.0 mg
Pyridoxine hydrochloride (*corresponding to Vitamin B_6 4.0 mg*)	4.9 mg	0.49 mg
Sodium pantothenate (*corresponding to Pantothenic acid 15.0 mg)*	16.5 mg	1.65 mg
Sodium ascorbate (*corresponding to Vitamin C 100 mg*)	113 mg	11.3 mg
Biotin	60 µg	6.0 µg
Folic acid	400 µg	40 µg
Cyanocobalamin	5.0 µg	0.5 µg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Soluvit N is a lyophilised, sterile, yellow powder of water-soluble vitamins for intravenous infusion.

Osmolality in 10 mL of water: approx. 490 mOsm/kg water
pH in 10 mL of water: 5.8

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Soluvit N is intended as a supplement in intravenous nutrition in order to meet the daily requirements of the water-soluble vitamins in adults, children, infants and neonates. Fat-soluble vitamins should also be administered to patients receiving prolonged parenteral nutrition.

4.2 Dose and method of administration

Dose

Adults and children weighing 10kg or more
The recommended daily dosage is the content of one vial.

Children, infants and neonates weighing less than 10kg
Children weighing less than 10kg should be given 1/10 of the content of one vial per kg body weight per day.

Method of administration
For instructions on dilution of the medicine, see Section 6.6

4.3 Contraindications
Known hypersensitivity to any of the components, for example, thiamine or methyl hydroxybenzoate.

4.4 Special warnings and precautions for use
Soluvit N must not be given undiluted.

Administering folic acid may obscure pernicious anaemia. The Soluvit N doses recommended are insufficient to correct severe vitamin deficiency states and may be insufficient in patients with markedly increased vitamin requirements. In patients receiving total parenteral nutrition (TPN), routine supplementation with both fat-soluble and water-soluble vitamins is recommended to prevent deficiency states and to obviate the need to speculate on individual vitamin status. Daily vitamin requirements must be calculated to avoid overdosage and toxic effects, especially with regards to vitamins A and D, and particularly in paediatric patients. In patients for whom total parenteral nutrition is continued for prolonged periods (months or years), periodic monitoring of blood vitamin levels should be considered.

To prevent excessive excretion of water-soluble vitamins, and for reasons of safety, daily dosage should be administered over a number of hours. See also the datasheet for Intralipid or Vitalipid N if Soluvit N is dissolved in these products.

Effects on laboratory tests
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. The risk of interference is higher in children and patients with renal impairment and increases with higher doses. When interpreting results of laboratory tests, possible biotin interference has to be taken into consideration, especially if a lack of coherence with the clinical presentation is observed (e.g. thyroid test results mimicking Graves' disease in asymptomatic patients taking biotin or false negative troponin test results in patients with myocardial infarction taking biotin). Alternative tests not susceptible to biotin interference should be used, if available, in cases where interference is suspected.
The laboratory personnel should be consulted when ordering laboratory tests in patients taking biotin.

4.5 Interactions with other medicines and other forms of interaction
Vitamin B_6 can reduce the effect of levodopa. Folic acid may lower the serum concentration of phenytoin.
Other drugs should not be added to Soluvit N dissolved in Intralipid or Vitalipid N, due to the possibility of physical incompatibilities (see product information for Intralipid and Vitalipid N).

4.6 Fertility, pregnancy and lactation
Fertility
No clinical data available.

Pregnancy
The requirement of vitamins in pregnant women may be insufficient due to the patient's altered needs. Soluvit N has been administered to pregnant women with no adverse reactions reported.

Breast-feeding
The requirement of vitamins in lactating women may be insufficient due to the patient's altered needs.

4.7 Effects on ability to drive and use machines
No effects on the ability to drive and use machines are to be expected.

4.8 Undesirable effects
Allergic reactions including anaphylactic reactions may occur in patients hypersensitive to any component in the preparation, for example, folic acid, methyl parahydroxybenzoate or thiamine (frequency not known). There have been rare reports of anaphylactoid reactions following repeated injection of

preparations containing thiamine. Flushing, itching or burning of the skin may occur in patients susceptible to the effects of nicotinamide. Evaluable safety data from clinical trials with Soluvit N are limited. Adverse reactions that may be expected based on experience with other water-soluble vitamin compounds administered intravenously include: allergic reactions, including anaphylaxis; dermatological reactions including flushing, erythema and pruritus and CNS reactions including headache, dizziness and agitation.

4.9 Overdosage
The possibility of hypervitaminosis A and D should be considered if the contents of the Soluvit vial is dissolved in Vitalipid N.

For information on the management of overdose, contact the National Poisons Centre on 0800 POISON (0800 764 766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
ATC code: B05X C00

Soluvit N is a mixture of watersoluble vitamins in amounts normally absorbed from the oral diet and should have no pharmacodynamic effect besides maintaining or repleting the nutritional status.

5.2 Pharmacokinetic properties
When infused intravenously the watersoluble vitamins in Soluvit N are handled in a similar way to watersoluble vitamins from an oral diet.

5.3 Preclinical safety data
The safety evaluation is based mainly on clinical experience and documentation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Glycine
Methyl hydroxybenzoate
Sodium edetate

6.2 Incompatibilities
Soluvit N may only be added to or mixed with other medicinal products for which compatibility has been documented. See Section 6.6.

6.3 Shelf life
18 months as packed for sale

24 hours once reconstituted.

6.4 Special precautions for storage
Do not store above 25°C. Protect from light.

Once reconstituted, store 8°C - 15°C. Protect from light.

6.5 Nature and contents of container
Glass vials
Stopper for injection vial, chlorobutyl rubber

Carton of 10 vials.

6.6 Special precautions for disposal and other handling
Adults and children age 11 years and above:
The contents of one vial of Soluvit N are dissolved by adding 10 ml of:
1. Vitalipid N Adult
or 2. Intralipid 10%, Intralipid 20%, Intralipid 30%,
or 3. Water for Injections
or 4. Glucose solution for infusion (5%-50%)

Soluvit N may be added to parenteral nutrition admixtures containing carbohydrates, lipids, amino acids, electrolytes and trace elements provided that compatibility and stability have been confirmed.

Children below 11 years of age:
The contents of one vial are dissolved by adding 10 ml of:
1. Vitalipid N Infant (for children above 10 kg/bw)
or 2. Intralipid 10%, Intralipid 20%
or 3. Water for Injections
or 4. Glucose solution for infusion (5%-50%)

Children weighing less than 10 kg should be given 1 ml of the dissolved mixture per kg body weight per day. Children weighing 10 kg or more should be given 10 ml (one vial) per day.

Due to differences in the dosage regimes for Soluvit N and Vitalipid N Infant, the mixture 1 is not recommended for children weighing less than 10 kg.

Soluvit N may be added to parenteral nutrition admixtures containing carbohydrates, lipids, amino acids, electrolytes and trace elements provided that compatibility and stability have been confirmed.

7. MEDICINE SCHEDULE
General Sale Medicine

8. SPONSOR
Fresenius Kabi New Zealand Limited
60 Pavilion Drive
Mangere, Auckland 2022
New Zealand
Freecall: 0800 144 892
Fax: +64 9925 2721
Email: medical.information@fresenius-kabi.com

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8 September 1988

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25 June 2019