SOLUVIT N- thiamine mononitrate, riboflavin 5-phosphate sodium anhydrous, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, sodium pantothenate, biotin, sodium ascorbate powder, for solution
Fresenius Kabi USA, LLC

Soluvit N
Powder for solution for infusion

Presentation

Soluvit N is a lyophilized, sterile, yellow mixture of water soluble vitamins for intravenous infusion. Qualitative and Quantitative Composition

One vial of Soluvit N contains:

Active ingredients	***Quantity***	***1 ml of reconstituted Soluvit N contains:***
Thiamine mononitrate (Corresponding to Vitamin B_1 2.5 mg)	3.1 mg	0.31 mg
Riboflavine sodium phosphate (Corresponding to Vitamin B_2 3.6 mg)	4.9 mg	0.49 mg
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	0.40 mg	40 µg
Cyanocobalamin	5.0 µg	0.5 µg

For the full list of excipients, see section list of excipients.

- Osmolality in 10 ml of water: approx. 490 mosm/kg water
- pH in 10 ml of water: 5.8

Therapeutic indications

Soluvit N is indicated in adult patients and children as a supplement in intravenous nutrition to meet the daily requirements of water soluble vitamins.

Posology and method of administration

Posology

Adults:

For adult patients and children weighing 10 kg or more, the recommended daily dosage is the content of one vial.

Infants:

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

Contraindications

Known hypersensitivity to any of the components, e.g. thiamine or methyl parahydroxybenzoate.

Special warning and special precaution for use

Soluvit N must not be given undiluted.

When Soluvit N is diluted with water based solutions, the admixture should be protected from light. This is not necessary if Soluvit N is diluted with Intralipid because of the protective effect of the fat emulsion.

Interference with clinical 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.

Interaction with other medicinal products and other forms of interaction

Folic acid may lower the serum concentration of phenytoin and obscure pernicious anaemia.

Vitamin B_6 can reduce the effect of levodopa.

Fertility, pregnancy and lactation

Animal reproduction studies or clinical investigations during pregnancy have not been carried out with Soluvit N. There are, however, published reports on safe administration

of water soluble vitamins in this patient group.

Effects on ability to drive and use machines

Not relevant.

Undesirable effects

Allergic reactions including severe (anaphylactic) reactions may occur in patients hypersensitive to any component of the preparation, e.g. folic acid, thiamine or methyl parahydroxybensoate (frequency not known).

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 the national reporting system.

Overdose

No adverse effects of an overdose of water soluble vitamins have been reported, with exception of cases of extremly high parenteral doses. Overdoses caused by parenteral preparations for nutritional supplement of water soluble vitamins have not been reported.

No specific treatment is needed. See also section Contraindications.

List of excipients

Glycine (Aminoacetic acid)

Disodium edetate.

Methyl parahydroxybenzoate

Incompatibilities

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

Shelf-life of the medicinal product as packed for sale

18 months

Shelf-life after mixing

Chemical and physical in-use stability after dilution has been demonstrated for 24 hours at 25°C. From a microbiological point of view, the product should be used immediately. 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.

Special precautions for storage

Do not store above 25°C. Protect from light.

Instructions for use/handling, and disposal

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%, Structolipid

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.

Disposal

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

Manufacturer:

Fresenius Kabi AB, Uppsala, Sweden

March 2019

FRESENIUS KABI

PACKAGE LABEL – PRINCIPAL DISPLAY – Soluvit N Vial Label

Soluvit N

Powder for solution for infusion

Soluvit N

Powder for solution for infusion

1 vial contains: Vitamin B_1 2.5 mg – Vitamin B_2 3.6 mg – Nicotinamide 40 mg – Vitamin B_6 4.0 mg – Pantothenic acid 15.0 mg – Vitamin C 100 mg – Biotin 60 µg – Folic acid 0.4 mg – Vitamin B_{12} 5.0 µg.

Additive to infusion fluids after dissolution. See package insert.
Do not store above 25 °C. Protect from light.

Batch No/Use before.:
Manuf. date:

330 608

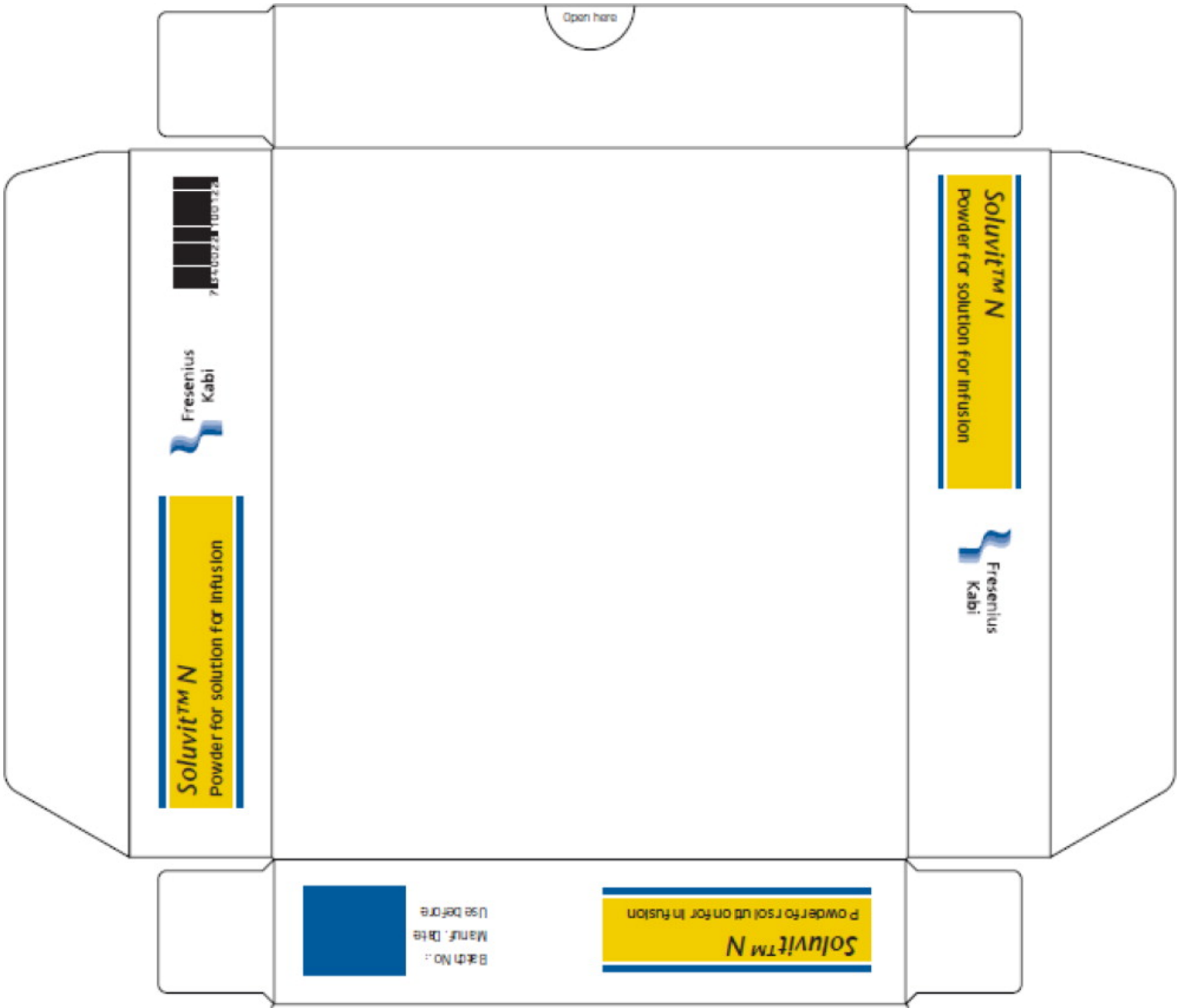
Fresenius Kabi AB, Uppsala, Sweden

PACKAGE LABEL – PRINCIPAL DISPLAY – Soluvit N Carton

Soluvit™ N

Powder for solution for infusion

10 Vials



Soluvit™ N

Powder for solution for infusion

Fresenius Kabi

10 vials

One vial contains:
Thiamine mononitrate 3.1 mg (corresponding to Vitamin B_1 2.5 mg), Riboflavine sodium phosphate 4.9 mg (corresponding to Vitamin B_2 3.6 mg), Nicotinamide 40 mg, Pyridoxine hydrochloride 4.9 mg (corresponding to Vitamin B_6 4.0 mg), Sodium pantothenate 16.5 mg (corresponding to pantothenic acid 15.0 mg), Sodium ascorbate 113 mg (corresponding to Vitamin C 100 mg), Biotin 60 µg, Folic acid 0.40 mg, Cyanocobalamin 5.0 µg, Glycine 300 mg, Disodium edetate 0.5 mg, Methylparahydroxy-benzoate 0.5 mg.

Additive to infusion fluids after dissolution. See package insert.

Do not store above 25 °C. Protect from light.

Keep out of reach of children.

Additions should be made aseptically.

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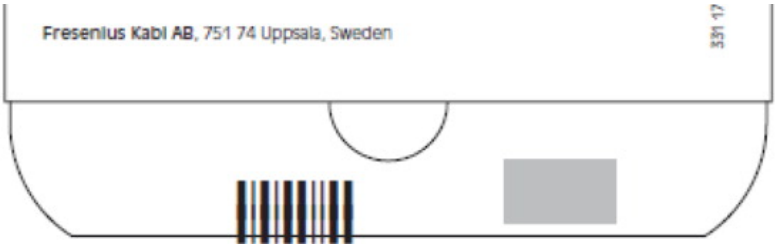

SOLUVIT N

thiamine mononitrate, riboflavin 5-phosphate sodium anhydrous, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, sodium pantothenate, biotin, sodium ascorbate powder, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-077
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
thiamine mononitrate (UNII: 8K0I04919X) (thiamine ion - UNII:4ABT0J945J)	THIAMINE	1.581 mg in 1 mL
riboflavin 5'-phosphate sodium anhydrous (UNII: 957E53WV42) (riboflavin 5'-phosphate - UNII:7N464URE7E)	riboflavin 5'-phosphate	2.45 mg in 1 mL
niacinamide (UNII: 25X51I8RD4) (niacinamide - UNII:25X51I8RD4)	niacinamide	20.0 mg in 1 mL
pyridoxine hydrochloride (UNII: 68Y4CF58BV) (pyridoxine - UNII:KV2JZ1BI6Z)	pyridoxine hydrochloride	2.45 mg in 1 mL
folic acid (UNII: 935E97BOY8) (folic acid - UNII:935E97BOY8)	folic acid	0.216 mg in 1 mL
cyanocobalamin (UNII: P6YC3EG204) (cyanocobalamin - UNII:P6YC3EG204)	cyanocobalamin	2.775 ug in 1 mL
sodium pantothenate (UNII: OES0R93F0C) (pantothenic acid - UNII:19F5HK2737)	sodium pantothenate	8.25 mg in 1 mL
biotin (UNII: 6SO6U10H04) (biotin - UNII:6SO6U10H04)	biotin	30.0 ug in 1 mL
sodium ascorbate (UNII: S033EH8359) (ascorbic acid - UNII:PQ6CK8PD0R)	ascorbic acid	56.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
edetate disodium (UNII: 7FLD91C86K)	
glycine (UNII: TE7660XO1C)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:65219-077-15	10 in 1 CARTON	07/07/2023	
1		2 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		07/07/2023	

Labeler - Fresenius Kabi USA, LLC (013547657)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi USA, LLC		840771732	ANALYSIS(65219-077) , MANUFACTURE(65219-077)

Revised: 7/2023 Fresenius Kabi USA, LLC