SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Soluvit N

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Thiamine Mononitrate	3.1 mg
Sodium Riboflavine Phosphate	4.9 mg
Nicotinamide	40 mg
Pyridoxine Hydrochloride	4.9 mg
Sodium Pantothenate	16.5 mg
Sodium Ascorbate	113 mg
Biotin	60 micrograms (0.06 mg)
Folic Acid	0.4 mg
Cyanocobalamin	5 micrograms (0.005 mg)

One vial of Soluvit N contains the following quantities of water-soluble vitamins;

Vitamin B1	2.5 mg
Vitamin B2	3.6 mg
Nicotinamide	40 mg
Vitamin B6	4 mg
Pantothenic acid	15 mg
Biotin	60 micrograms
Folic acid	0.4 mg
Vitamin B12	5 micrograms
Vitamin C	100 mg

Excipients with known effect: Methylparaben (E218) 0.5 mg per vial. For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for solution for infusion.

Lyophilised sterile yellow powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

Adults:

For adult patients and children weighing 10 kg or more the recommended daily dosage is the contents 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.

Method of Administration

See 6.6. "Special precautions for disposal and handling".

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Soluvit N must not be given undiluted.

For special precautions during pregnancy, see section 4.6.

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.

4.5 Interaction with other medicinal products and other forms of interaction

Pyridoxine (Vitamin B_6) 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.

4.6 Fertility, pregnancy and lactation

Soluvit N is a supplement in TPN regimens, providing water-soluble vitamins. No hazard is expected if used in pregnancy at the recommended dosage, covering the daily requirements of vitamins B_1, B_2, B_6, B_{12} and C.

4.7 Effects on ability to drive and use machines

Soluvit N has no influence on the ability to drive and use machines.

4.8 Undesirable effects

MedDRA system organ class	**Very common ≥ 1/10**	**Common ≥1/100 to <1/10**	**Uncommon ≥1/1,000 to <1/100**	**Rare ≥1/10,000 to <1/1, 000**	**Very rare <1/10, 000**	**Not known (cannot be estimated from the available data)**
Immune system disorders						Anaphylactic reaction

Reporting of suspected adverse reactions
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website (www.health.gov.il) which links to an online form for reporting side effects, or by following this link: https://sideeffects.health.gov.il and by emailing the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

4.9 Overdose

In general overdosage with Soluvit N is unlikely. No clinically significant effects are envisaged if overdose should occur. However, treatment would be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Vitamins, ATC Code: B05XC

Soluvit N is formulated to supply water-soluble vitamins as part of a total parenteral nutrition regimen.

5.2 Pharmacokinetic properties

Soluvit N is a product without interest for pharmacokinetic studies.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to that already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycine (Aminoacetic Acid)

Methylparaben E218

Disodium Edetate

Water for Injections

6.2 Incompatibilities

Soluvit N must only be added to or mixed with other medicinal products for which compatibility has been documented. Please refer to section 6.6.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Vial for injection, glass type I.
Stopper for injection vial, chlorobutyl rubber.
Pack Size: 1 x 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 MANUFACTURER

Fresenius Kabi AB, Uppsala, Sweden

8 REGISTRATION HOLDER

Cure Medical & Technical Supply
6 Hashiloach St., POB 3340, Petach-Tikva

9 REGISTRATION NUMBER(S)

102-29-26397-05

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