

Soluvit N

Multivitamin

Powder for solution for infusion

Composition

Each vial (\pm 166 mg) 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 mg)	
Sodium ascorbate	113 mg
(Corresponding to Vitamin C 100 mg)	
Biotin	60 μ g
Folic acid	0.40 mg
Cyanocobalamin	5.0 μ g

Action :

Pharmacodynamic Properties

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.

Pharmacokinetics Properties

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

Indication

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

Posology and Method in administration

Dosage

Adult

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.

Administration

Instructions for use / handling and disposal

Adults and children age 11 years and above :

The content of one vial of Soluvit N are dissolved by adding 10 ml of:

1. Vitalipid N Adult in Intralipid 10%
- or 2. Vitalipid N Adult in Intralipid 20%
- or 3. Water for injections
- or 4. Glucose solution for infusion (5% - 50%).

Children below 11 years of age :

The content of one vial are dissolved by adding 10 ml of:

1. Vitalipid N Infant (for children above 10 kg/bw)
- or 2. Intralipid 10%
- 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 regimen for Soluvit N and Vitalipid N Infant, the mixture 1 is not recommended for children weighing less than 10 kg.

When Soluvit N is given in a glucose solution, the admixture should be protected from light. This is not necessary if Soluvit N is given in Intralipid, due to the protective effect of the fat emulsion.

Warning and Precautions

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

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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.

Side 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 parahydroxybenzoate (frequency not known).

Pregnancy and Lactation

Animal reproduction studies or clinical investigations during pregnancy have not been carried out with Soluvit N.

Effects in ability to drive and use machines
Not relevant

Contra Indications

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

Drug Interaction

Folic acid may lower the serum concentration of phenytoin and obscure pre-nicious anaemia. Vitamin B6 can reduce the effect of levodopa.

Overdosage

No adverse effect of an overdose of water-soluble vitamins have been reported, with exception of cases of extremely high parenteral doses. Overdose caused by parenteral preparations for nutritional supplement of watersoluble vitamins have not been reported.

No specific treatment is needed. See also Contraindications.

Incompatibilities

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

Storage

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

Shelf life

18 months

Presentation

Box, 10 vials @ ± 166 mg
Reg. No. : DK1574502280A1

ON MEDICAL PRESCRIPTION ONLY
HARUS DENGAN RESEP DOKTER

Manufactured by:

Fresenius Kabi SSPC, Wuxi-China

For :

Fresenius Kabi AB, Uppsala, Sweden

Imported by:

PT. Fresenius Kabi Combiphar

Bandung - Indonesia



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