APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S3

1 NAME OF MEDICINE

SOLUVIT® NOVUM (lyophilised powder for solution for infusion)

Pharmaceutical form

Powder for solution for infusion

Lyophilised sterile yellow powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 mL contains:

Thiamine mononitrate corresponding to thiamine HCl	3,2 mg
Sodium riboflavine phosphate corresponding to riboflavin	3,6 mg
Nicotinamide	40,0 mg
Pyridoxine hydrochloride corresponding to pyridoxine	4,0 mg
Sodium pantothenate corresponding to pantothenic acid	15,0 mg
Sodium ascorbate corresponding to ascorbic acid	100,0 mg
Biotin	60,0 µg
Folic acid	0,4 mg
Cyanocobalamin	5,0 µg

Sugar free.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for solution for infusion.

Lyophilized sterile yellow powder

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

SOLUVIT NOVUM is intended as a supplement in intravenous nutrition, in order to meet the daily requirements of the water-soluble vitamins in adults and children. It is not intended for use in the treatment of suspected or established vitamin deficiency states.

4.2 Posology and method of administration

The daily requirements of the majority of adult patients and children weighing **10 kg** or more are met by the contents of one vial. Children weighing less than 10 kg should receive 1/10 of the contents of one vial per kg body weight. The lyophilised powder is reconstituted as described below and either added to INTRALIPID® or to glucose solution for infusion.

Adults and children over 10 kg:

If SOLUVIT NOVUM is to be added to INTRALIPID the contents of one vial are reconstituted by the aseptic addition of 10 mL of either VITALIPID® NOVUM ADULT or INTRALIPID 10 % or 20 %.

If SOLUVIT NOVUM is to be added to glucose solution for infusion, electrolyte free (5 % - 60 %) the contents of one vial are reconstituted by the aseptic addition of 10 mL of either water for injection or glucose solution for infusion, electrolyte free.

Children under 10 kg:

If SOLUVIT NOVUM is to be added to INTRALIPID the contents of one vial are reconstituted by the aseptic addition of 10 mL INTRALIPID 10 % or 20 %. If SOLUVIT NOVUM is to be added to glucose solution for infusion, electrolyte free (5 % - 60 %) the contents of one vial are

reconstituted by the aseptic addition of 10 mL of either water for injection or glucose solution for infusion, electrolyte free. 1 mL of this reconstituted solution should be given per kg body weight. **The reconstituted SOLUVIT NOVUM should be added to the infusion solution aseptically immediately before the start of the infusion and used within 24 hours.**

Admixtures containing SOLUVIT NOVUM in glucose solutions should be protected from light.

SOLUVIT NOVUM may not be reconstituted with, or added to any other products not specifically mentioned in this package insert, unless compatibility has been documented.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

SOLUVIT NOVUM must not be given undiluted.

Allergic reactions, including anaphylactic reactions may occur in patients hypersensitive to any component of the preparation, e.g. folic acid, thiamine or methyl parahydroxybenzoate

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.

The SOLUVIT NOVUM 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 should be calculated to avoid overdosage and toxic effects, especially with regard 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.

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 medicines and other forms of interaction

Folic acid may lower the serum concentration of phenytoin and there is a possibility that such an effect could also occur with barbiturates and antiepileptics. Vitamin B_6 may reduce the effect of levodopa.

4.6 Fertility, pregnancy and lactation

Pregnancy:

The requirement of vitamins in pregnant and lactating women may be insufficient due to the patient's altered needs. SOLUVIT NOVUM has been administered to pregnant women with no adverse reactions reported.

Breastfeeding

Folic acid is excreted in breastmilk. No adverse effects have been seen in breast-fed infants whose mothers were receiving folic acid.

4.7 Effects on ability to drive and use machines

Dizziness has been reported in some patients. Patients should be advised not to drive if this happens.

4.8 Undesirable effects

Summary of the safety profile (see also section 4.4)

Allergic reactions, including anaphylactic reactions, may occur in patients hypersensitive to any component in the preparation, e.g. folic acid, methyl parahydroxybenzoate, thiamine or cyanocobalamin (frequency not known). Other side effects that have been reported with water-soluble vitamin compounds administered intravenously include dermatological reactions including flushing, erythema and pruritus and CNS reactions including headache, dizziness and agitation.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important.
It allows continued monitoring of the benefit/risk balance of the medicine.
Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form",** found online under SAHPRA's publications:

http://www.sahpra.org.za

Healthcare providers should also report adverse reactions to the Holder of Certificate of Registration, **Fresenius Kabi South Africa (Pty) Limited.**

The contact details for our national reporting system are:

Email: safety.fksa@fresenius-kabi.com

Tel: +27 11 545 0000

Emergency: 0860 203 900

4.9 Overdose

None known

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class of medicine: A. 22.1.4 Vitamins B-complex with Vitamin C

Pharmacotherapeutic group: Infusion concentrate (substance) of water- soluble vitamins,

ATC code: B05X C00

Mechanism of action

Multi-vitamin preparations for intravenous administration are essential for use in long-term total parenteral nutrition (TPN) therapy. SOLUVIT NOVUM is composed according to the recommendations of the American Medical Association (1975) for parenteral vitamin solutions to adults. SOLUVIT NOVUM contains nine water soluble vitamins. The formulation SOLUVIT NOVUM has no other pharmacodynamic effect other than the vitamin effect per se.

5.2 Pharmacokinetic properties

When infused intravenously the water-soluble vitamins in SOLUVIT NOVUM are handled in a similar way to water-soluble 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 (amino acetic acid)

Disodium edetate

Methyl parahydroxybenzoate

6.2 Incompatibilities

SOLUVIT NOVUM 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

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.

6.4 Special precautions for storage

Store at or below 25 °C. Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

Vial for injection, glass type I

Stopper for injection vial, black chlorobutyl rubber

1 x 10 mL vial

10 x 10 mL 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 NOVUM 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 NOVUM 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 NOVUM and Vitalipid N Infant, the mixture 1 is not recommended for children weighing less than 10 kg.

SOLUVIT NOVUM 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

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

U/22.1.4/200

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 July 1991

10 DATE OF REVISION OF TEXT

04 May 2021