Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solivito N Powder for Concentrate for Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One 10 ml vial contains:

Thiamine Nitrate	3.1 mg
Riboflavine Sodium Phosphate	4.9 mg
Nicotinamide	40 mg
Pyridoxine Hydrochloride	4.9 mg
Sodium Pantothenate	16.5 mg
Biotin	60 micrograms
Folic Acid	0.4 mg
Cyanocobalamin	5.0 micrograms
Sodium Ascorbate	113 mg

One vial of Solivito N contains the following quantities of water-soluble vitamins.

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
Biotin	60 micrograms
Folic acid	0.4 mg
Vitamin B_{12}	5.0 micrograms
Vitamin C	100 mg

Excipients – contains methyl parahydroxybenzoate (E218) 0.5mg per vial.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for concentrate for solution for infusion.

Sterile, freeze dried yellow cake.

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

Solivito N is intended for use as a supplement in intravenous nutrition providing the daily requirements of water soluble vitamins in adults and children.

4.2 Posology and method of administration

Route of administration: Intravenous infusion after dilution, see section 6.6.

One vial of Solivito N should be infused over a minimum period of two to three hours in patients with normal renal function so as to minimise renal losses.

Recommended dosage for adults and children weighing 10kg or more
For adult patients and children weighing 10kg or more the recommended daily dosage is the contents of one vial.

Recommended dosage for infants and children under 10kg
Children weighing less than 10kg should be given 1/10 of the contents of one vial per kg body weight per day.

Recommended dosage for the elderly
No adjustment of the adult dosage should be required.

Solivito N may be added to parenteral admixtures containing carbohydrates, lipids, amino acids, electrolytes and trace elements provided that compatibility and stability have been confirmed (see section 6.6).

4.3 Contraindications

Hypersensitivity to the active substances (e.g. thiamine (B1)) or to any of the excipients (e.g methyl parahydroxybenzoate (E218)).

4.4 Special warnings and precautions for use

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.

Care should be taken in the administration of cyanocobalamin with some of the optic neuropathies.

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

The addition of the formulation to the infusion solution should be performed aseptically immediately before the start of the infusion, and the mixture used within 24 hours of preparation.

Folic acid may obscure pernicious anaemia.

Contains methyl parahydroxybenzoate. May cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.

4.5 Interaction with other medicinal products and other forms of interactions

Pyriodoxine (Vitamin B_6) can reduce the effect of levodopa. Folic acid may lower the serum concentration of phenytoin.

4.6 Fertility, pregnancy and lactation

Animal reproduction studies or clinical investigations during pregnancy have not been carried out with Solivito N. There are however published reports on safety administration of water soluble vitamins. No hazard is expected if used in pregnancy at the recommended dosage which covers the daily requirements of vitamins B_1, B_2, B_6, B12 and Vitamin C.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

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

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
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

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

4.9 Overdose

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

No adverse effects of an overdose of water soluble vitamins have been reported, with the exception of cases of extremely high parenteral doses. Overdoses caused by parenteral preparations for nutritional supplement of water soluble vitamins have not been reported. Volume overload is a possibility resulting in pulmonary however, it is rare to have an overdose reaction due to water soluble vitamins.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Vitamins
ATC Code: B05XC

Solivito N is formulated to supply water soluble vitamins as part of a total parenteral nutrition regimen in amounts normally absorbed from the oral diet. Solivito N should have no pharmacological effect besides maintaining or repleting the nutritional status.

5.2 Pharmacokinetic properties

When infused intravenously the water soluble vitamins in Solivito N 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 (Aminoacetic Acid)
Methyl Parahydroxybenzoate (E218)
Disodium Edetate
Water for Injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

Shelf life of medicinal product packaged 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.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.
Keep container in the outer carton in order to protect from light.
For storage conditions after mixing of the medicinal product, see section 6.3.

6.5 Nature and contents of container

10 ml Glass vial (Ph Eur - Type 1) with a Butyl rubber stopper and a flip-off cap each containing 484 mg lyophilised powder.
Pack size: 1 x 10 vials

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Solivito N should not be administered undiluted. See section 4.2

Compatibility and instructions for use

All additions should be made aseptically.

For Adults and Children weighing 10kg or more
The contents of one vial of Solivito N are dissolved by the aseptic addition of 10ml of one of the following:
(i) Vitlipid N Adult or for children under 11 years of age Vitlipid N Infant.

(ii) Intralipid 10%, 20% or 30%

(iii) Glucose Intravenous Infusion (5% - 50%*).

(iv) Water for Injections.

*The solution should be diluted down to 10-20% for administration via a peripheral line. No dilution is required if centrally administered.

The reconstituted mixtures (i) and (ii) should be aseptically transferred to Intralipid 10%, 20% or 30% for infusion. The reconstituted mixtures (iii) and (iv) should be added to either glucose solution (5% - 50%) or Intralipid 10%, 20% or 30%. In this way the basal requirements of the water-soluble vitamins are provided.

For Infants and Children under 10kg
The contents of one vial are dissolved by the aseptic addition of 10 ml of one of the following:

(i) Vitlipid N Infant.

(ii) Intralipid 10% or 20%.

(iii) Glucose Intravenous Infusion (5% - 50%*).

(iv) Water for Injections

*The solution should be diluted down to 10-20% for administration via a peripheral line. No dilution is required if centrally administered.

The basal requirements for water-soluble vitamins in children are provided by 1.0ml of this reconstituted mixture per kg bodyweight.

The reconstituted mixtures (i) and (ii) should be aseptically transferred to Intralipid 10% or 20% for infusion. The reconstituted mixtures (iii) and (iv) should be added to either glucose solution (5% - 50%) or to Intralipid 10% or 20%.

Storage after mixing
The addition of the formulation to the infusion solution should be performed aseptically immediately before the start of the infusion and the mixture should be used within 24 hours of preparation to prevent microbiological contamination.

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

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352
Germany

8 MARKETING AUTHORISATION NUMBER

PA2059/064/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 December 1999
Date of last renewal: 09 December 2009

10 DATE OF REVISION OF THE TEXT

October 2019