SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Solivito N Powder for Concentrate for Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

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

Excipients with known effect: methyl parahydroxybenzoate (E218) 0.5mg per vial.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for concentrate for solution for infusion.

Lyophilised sterile yellow powder.

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 and soluble vitamins in adults and children.

4.2 Posology and method of administration

Posology

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 10 kg or more

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

Recommended dosage for infants and children weighing under 10 kg

Children weighing less than 10 kg 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.

Method of Administration

For intravenous infusion after dilution.

For instructions on dilution of the medicinal product before administration, see section 6.6.

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

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

Solivito 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

Solivito 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
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:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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.

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.

5.2 Pharmacokinetic properties

Solivito 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)

Methyl- parahydroxy-benzoate

Disodium Edetate

Water for Injections

6.2 Incompatibilities

Solivito 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

18 months

6.4 Special precautions for storage

Store below 25°C

Keep the container in the outer carton in order to protect from light.

6.5 Nature and contents of container

10ml Glass Vial (Ph.Eur – Type I) with a butyl rubber stopper and a flip-off cap each containing 484mg lyophilised powder.

Pack Size: 1 x 10 vials.

6.6 Special precautions for disposal and other handling

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% or 20%.

(iii) Glucose intravenous infusion (5% - 60%).

(iv) Water for injections.

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% - 60%) or Intralipid 10% or 20%. In this way the basal requirements of the water-soluble vitamins are provided.

Solivito 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.

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% - 60%).

(iv) Water for Injection

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% - 60%) or to Intralipid 10% or 20%.

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

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 08828/0116

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/03/2009

10 DATE OF REVISION OF THE TEXT

29/05/2019