1. NAME OF THE MEDICINAL PRODUCT

Vitalipid N Adult, concentrate for solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	**Per ml**	
Retinolpalmitate	194.1 µg	
(corresponding to retinol)	99 µg	
Phytomenadione	15 µg	
Ergocalciferol	0.5 µg	
all-rac-α-Tocopherol	0.91 mg	
Corresponding to:		
Vitamin A	99 µg	(330 IU)
Vitamin D_2	0.5 µg	(20 IU)
Vitamin E	0.91 mg	(1 IU)
Vitamin K_1	15 µg	

- pH: approx. 8
- Osmolality: approx. 300 mosm/kg water

3. PHARMACEUTICAL FORM

Concentrate for solution for infusion.

Vitalipid N Adult is a sterile oil-in-water emulsion containing fat-soluble vitamins in the oil phase.

For excipients, see section 6.1

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Vitalipid N Adult is indicated in adult patients and children from 11 years of age as a supplement in intravenous nutrition to meet the daily requirements of the fat-soluble vitamins A, D_2, E and K_1.

4.2 Posology and method of administration

For adult patients and children from 11 years of age, the recommended daily dosage is 10 ml (one ampoule).

See section 6.6.

4.3 Contraindications

Hypersensitivity to egg-, soya- or peanut protein or to any of the active substances or excipients.

4.4 Special warnings and special precautions for use

This medicinal product contains soya-bean oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut.

Vitalipid N Adult must not be given undiluted.

4.5 Interaction with other medicaments and other forms of interaction

The presence of trace elements may cause some degradation of vitamin A. Retinol (vitamin A) may be broken down by exposure to ultraviolet light. Vitamin K_1 interacts with anticoagulants of the coumarin type.

4.6 Pregnancy and lactation

Animal reproduction studies or clinical investigations during pregnancy have not been made with Vitalipid N Adult. There are, however, published reports on safe administration of fat-soluble vitamins in this patient group.

However, the intake of more than 8.000 IU of Vitamin A is not recommended during pregnancy due to the risk of birth defects.

4.7 Effects on ability to drive and use machines

No effects on the ability to drive and operate machines are to be expected.

4.8 Undesirable effects

No adverse effects related to Vitalipid N Adult have been reported.

4.9 Overdose

Overdoses of fat-soluble vitamins may lead to toxicity syndromes, but there is no evidence of any toxicity at the dosages recommended.

No adverse effects of a single overdose of fat-soluble vitamins should occur. No specific treatment is needed.

After prolonged infusion of an overdose of Vitamin D, elevated serum concentrations of Vitamin D metabolites may occur. This may cause osteopenia.

Rapid infusion of Vitamin K_1 in colloid water solution may provoke flushing, bronchospasm, tachycardia and hypotension. This has not been reported after infusions of Vitalipid N Adult.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Concentrate for solution for infusion
ATC-code: B05X C

Vitalipid N Adult is a mixture of fat-soluble vitamins in amounts normally absorbed from the oral diet and should have no pharmacodynamic effect besides maintaining or repleting the nutritional status.

5.2 Pharmacokinetic properties

When infused intravenously, the fat-soluble vitamins in Vitalipid N Adult are metabolized in a similar way to fat-soluble vitamins from an oral diet.

5.3 Preclinical safety data

The safety evaluation of Vitalipid N Adult is based mainly on clinical experience.

The teratogenicity of vitamin A in high doses is well documented in animals. Provided the dosage recommendations for Vitalipid N Adult are followed there should be a satisfactory safety margin for pregnant women.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified soybean oil
Purified egg phospholipids
Glycerol (anhydrous)
Sodium hydroxide 1 M .
(Water for injections, Ph. Eur., is used for dilution.)
Water for injections
Nitrogen

6.2 Incompatibilities

Vitalipid N Adult 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

Shelf-life of the medicinal product as packaged for sale

24 months

6.4 Special precautions for storage

Store below 25ºC.
Protect from light. Do not freeze.

Storage after mixing
See section 6.6.

6.5 Nature and contents of container

Type I glass ampoules.

Pack size:
10 x 10 ml.

6.6 Instructions for use/handling

Vitalipid N Adult must not be given undiluted.

Compatibility and instructions for use

All additions should be made aseptically.

10 ml (1 ampoule) of Vitalipid N Adult is added to 500 ml of Intralipid. To ensure a homogeneous admixture, the bottle should be inverted a couple of times immediately before the infusion.

Vitalipid N Adult 10 ml (1 ampoule) can also be added to Structolipid.

Vitalipid N Adult can be used to dissolve Soluvit N. The contents of one vial of Soluvit N is dissolved by the addition of 10 ml of Vitalipid N Adult and added to Intralipid or Structolipid.

Vitalipid N Adult is also used as a complement in TPN mixing in plastic bag.

Storage after mixing

The addition of Vitalipid N Adult to Intralipid should be made within one hour before the start of the infusion, and the infusion should be completed within 24 hours from preparation to prevent microbiological contamination. The left-over contents of opened bottles/vials/ampoules should be discarded and not kept for later use.

7. MARKETING AUTHORISATION HOLDER

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT