1. NAME OF THE MEDICINAL PRODUCT

Vitalipid N Infant, concentrate for solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	**Per ml**	
Retinolpalmitate	135.3 µg	.
(corresponding to retinol)	69 µg	
Phytomenadione	20 µg	
Ergocalciferol	1.0 µg	
all-rac-α-Tocopherol	0.64 mg	
Corresponding to:		
Vitamin A	69 µg	(230 IU)
Vitamin D_2	1.0 µg	(40 IU)
Vitamin E	0.64 mg	(0.7 IU)
Vitamin K_1	20 µg	

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

For excipients, see section 6.1

3. PHARMACEUTICAL FORM

Concentrate for solution for infusion.

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Vitalipid N Infant is indicated in infants and children up to 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

4 ml/kg bodyweight/day to preterm and low birth weight infants up to 2.5 kg bodyweigh, and 10 ml/day for all infants and children weighing more than 2.5 kg up to 11 years of age.

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.

Vitaipid N Infant 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

Not applicable.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

No adverse effects related to Vitalipid N Infant 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 Infant.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Vitalipid N Infant 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 Infant 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 Infant is based mainly on clinical experience.

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 Infant 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 ampoule.

Pack size:
10 x 10 ml.

6.6 Instructions for use and handling

Vitalipid N Infant must not be given undiluted.

Compatibility and instructions for use

All additions should be made aseptically.

Up to 10 ml (1 ampoule) of Vitalipid N Infant is added to Intralipid 10% or 20%. To ensure a homogeneous admixture, the bottle should be inverted a couple of times immediately before the infusion.

Vitalipid N Infant can be used to dissolve Soluvit Infant. The contents of one vial of Soluvit Infant is dissolved by the addition of 10 ml of Vitalipid N Infant and added to Intralipid 10% or 20%.

For children weighing more than 10 kg Vitalipid N Infant can also be used to dissolve Soluvit N. For children less than 10 kg/bw the dissolution with Soluvit N is not recommended due to differences in dosage regimens.

Storage after mixing

The addition of Vitalipid N Infant to Intralipid 10% or 20% 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