SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

VITALIPID N INFANT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

		1 ml contains:	10 ml contains:
Retinolpalmitate corresponding to retinol	Vitamin A	135.3 micrograms (corresponding to 69 micrograms Retinol (230 IU)	1353 micrograms (corresponding to 690 micrograms Retinol (2,300 IU)
Ergocalciferol	Vitamin D2	1 microgram (40 IU)	10 micrograms (400 IU)
dl-alpha-tocopherol	Vitamin E	0.64 mg (0.7 IU)	6.4 mg (7 IU)
Phytomenadione	Vitamin K1	20 micrograms	200 micrograms

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

Excipients with known effect: purified soybean oil.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for solution for IV infusion.
A sterile, oil-in-water white 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 requirement of the fat-soluble vitamins A, D2, E, K1.

4.2. Posology and method of administration

4 ml/kg bodyweight/day to preterm and low birth weight infants up to 2.5 kg bodyweight, 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

Vitalipid N Infant should not be administered undiluted.
Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 or to egg, soya or peanut protein.

4.4. Special warnings and special precautions for use

- This medicinal product contains soybean oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut.
- The addition of the formulation to the infusion solutions should be made aseptically and the solution used within 24 hours of preparation. See section 6.6

4.5. Interaction with other medicinal products and other forms of interaction

Vitamin K1 may interact with anticoagulants of the coumarin type.

4.6. Fertility, 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.

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.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il/

and emailed to the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

4.9. Overdose

In general, overdosage with Vitalipid N Infant is unlikely. If chronic overdosage occurred, symptoms such as headache, nausea, vomiting and drowsiness may be observed. In addition to withdrawal of Vitalipid N Adult, therapy should focus on treatment of symptoms. Spontaneous reversal of any symptoms should occur without requiring a specific antidote.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Vitamins
ATC code: B05XC

Vitalipid N Infant is formulated to supply the fat soluble vitamins A1, D2, E and K1 for intravenous infusion.

5.2. Pharmacokinetic properties

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

5.3. Pre-clinical Safety Data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Purified Soybean Oil
Glycerol (Anhydrous)
Purified Egg Phospholipids
Sodium Hydroxide
Water For Injection
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

The expiry date of the product is indicated on the packaging materials.

6.4. Special precautions for storage

Store below 25°C.
Do not freeze.
Protect from light.

For storage conditions after dilution of the medicinal product, see section 6.6.

6.5. Nature and contents of container

10 ml Ampoules (Colorless glass Type 1)
Pack Size: 10 x 10 ml.

6.6. Special precautions for disposal

Vitalipid N Infant must not be administered 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 homogenous admixture, the container 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 body weight 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 ampoules should be discarded and not kept for later use.

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

7. MANUFACTURER

Fresenius Kabi AB
SE-751 74 Uppsala, Sweden

8. LICENSE HOLDER

Cure Medical & Technical Supply
6 Hashiloach St., Pob 3340, Petach-Tikva

9. REGISTRATION NUMBER

105-39-26395-05

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