SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

VITALIPID N ADULT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

		1 ml contains:	10 ml contains:
Retinol palmitate (corresponding to Retinol)	Vitamin A	194.1 micrograms (corresponding to 99 micrograms Retinol (330 IU))	1941 micrograms (corresponding to 990 micrograms Retinol (3,300 IU))
Ergocalciferol	Vitamin D2	0.5 micrograms (20 IU)	5 micrograms (200 IU)
dl-alpha-tocopherol	Vitamin E	0.91 mg (1 IU)	9.1 mg (10 IU)
Phytomenadione	Vitamin K1	15 micrograms	150 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 adult is indicated in adult patients and children from 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

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 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 soybean and peanut.
- Vitalipid N Adult must not be administered undiluted.
- The addition of the formulation to the infusion solutions should be made aseptically and the solution used within 24 hours of preparation.

4.5. Interaction with other medicaments and other forms of interactions

This preparation contains Vitamin K1, which may interact with anticoagulants of the coumarin type.

4.6. Pregnancy and lactation

No animal studies have been performed with Vitalipid N Adult. However, there are published reports on safe and successful use of vitamins as part of a total parenteral nutrition regimen during pregnancy in this patient group.

The intake of more than 8000 IU of vitamin A is not recommended during pregnancy due to the risk of birth defects especially if taken during the first trimester. If the patient is pregnant or is likely to become pregnant the total daily dose needs to be evaluated considering the concomitant intake of vitamin A from food. Provided the dosage recommendations for Vitalipid N Adult are followed there should be a satisfactory safety margin for pregnant women.

4.7. Effects on ability to drive and use machines

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

4.8. Undesirable effects

No adverse effects related to Vitalipid N Adult 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 Adult 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.

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: Vitamins
ATC code: B05XC

Vitalipid N Adult is formulated to supply the fat soluble vitamins A_1, D_2, E and K_1 for intravenous infusion in amounts normally absorbed from the oral diet and should have 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 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 Adult must not be mixed with other medicinal products except those listed in 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 Instructions for use/handling

Vitalipid N Adult must not be administered 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 homogenous 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 content 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 total parenteral nutrition mixing in a 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 content 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

105-38-26396-05

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