Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vitlipid N Adult concentrate for emulsion for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

		Each 1 ml of emulsion contains:	Each 10 ml of emulsion contains:
Retinol palmitate corresponding to retinol	(Vitamin A)	99 micrograms (330 IU)	990 micrograms (3,300 IU)
Ergocalciferol	(Vitamin D_2)	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 K_1)	15 micrograms	150 micrograms

Excipients: Each 10ml contains 1g of purified soyabean oil

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Concentrate for emulsion for infusion
A sterile, oil-in-water white emulsion containing fat soluble vitamins in the oil phase.
pH: approx. 8
Osmolality: approx. 300 mosm/kg water

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Vitlipid 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 intravenous infusion after dilution, see section 6.6.

Recommended daily dosage for adults and children aged 11 to 18 years
One ampoule (10 ml) Vitlipid N Adult added to 500 ml Intralipid 10%, 20% or 30%.

Recommended dosage for the elderly
No adjustment of the adult dosage is required.

Do not exceed the recommended dose.

Method of administration
For intravenous infusion after dilution, 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 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.

Vitlipid 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 medicinal products and other forms of interactions

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, may interact with anticoagulants of the coumarin type.

4.6 Fertility, pregnancy and lactation

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

The intake of more than 8,0000 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 must also be considered. Provided the dosage recommendations for Vitlipid N Adult are followed there should be a satisfactory safety margin for pregnant women.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

No adverse effects related to Vitlipid 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. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance. Website: www.hpra.ie.

4.9 Overdose

In general overdosage with Vitlipid N Adult is unlikely.

However, if chronic overdosage occurred symptoms such as headache, nausea, vomiting and drowsiness may be observed. In addition to withdrawal of Vitlipid 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 Vitlipid N Adult.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamins
ATC code: B05XC

Vitlipid 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 no pharmacodynamic effect besides maintaining or repleting the nutritional status.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

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

The teratogenicity of vitamin A in high doses is well documented in animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Soybean Oil
Purified Egg Phospholipids
Glycerol (anhydrous)
Sodium Hydroxide (for pH adjustment)
Water for Injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

Shelf life of medicinal product as packaged for sale: 2 years
In-use shelf life: 24 hours.

6.4 Special precautions for storage

Store below 25°C
Do not freeze
Keep container in the outer carton to protect from light.
For storage conditions after dilution of the medicinal product, see section 6.6

6.5 Nature and contents of container

10ml Glass (Ph Eur, Type 1) ampoule containing white, oil in water emulsion.
Pack size: 10 x 10 ml

6.6 Special precautions for disposal and other handling

Vitlipid N Adult must not be administered undiluted.

Compatibility and instructions for use:

All additions should be made aseptically.

10 ml (1 ampoule) of Vitlipid 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.

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

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

Storage after mixing
The addition of Vitlipid N Adult 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 the opened bottles/vials/ampoules should be discarded and not kept for late use.

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352
Germany

8 MARKETING AUTHORISATION NUMBER

PA2059/067/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 16 May 2008

10 DATE OF REVISION OF THE TEXT

April 2022