SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vitlipid N Adult, concentrate for emulsion for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

		1 ml contains:	**10 ml contains:**
Retinolpalmitate 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

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 emulsion for infusion.
A sterile, oil-in-water white emulsion containing fat soluble vitamins in the oil phase.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Vitlipid N Adult is indicated in adults and children from 11 years of age as a supplement in intravenous nutrition to meet the daily requirements for the fat soluble vitamins A_1, D_2, E and K_1.

4.2 Posology and method of administration

Posology

Do not exceed the recommended dose.

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% or 20%.

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

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 soybean 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 interaction

This preparation contains Vitamin K1, which 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 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 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 the yellow card the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

In general, overdosage with Vitlipid N Adult is unlikely. 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. 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
Purified egg phospholipids
Glycerol (anhydrous)
Sodium hydroxide
Water for injections

6.2 Incompatibilities

Vitlipid N Adult must not be mixed with other medicinal products except those listed 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 container to 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 glass (Ph.Eur, Type 1) ampoule containing white, oil in water emulsion.
Pack Size: 10 x 10 ml.

6.6 Special precautions for disposal

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 container 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.

Vitlipid N Adult is also used as a complement in total parenteral nutrition mixing in a plastic bag.

Storage after mixing

The addition of Vitlipid 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.

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

7 MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

PL 08828/0124

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 June 1999
Date of latest renewal: 18 March 2009

10 DATE OF REVISION OF THE TEXT

30/03/2022