SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vitlipid N Infant concentrate for emulsion for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

		1 ml contains:	**10 ml contains:**
Retinolpalmitate corresponding to retinol	Vitamin A	69 micrograms (230 IU)	690 micrograms (2,300 IU)
Ergocalciferol	Vitamin D_2	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 K_1	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 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 Infant is indicated in infants and children up to 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

Recommended daily dosage for infants and children up to 11 years of age

4 ml/kg bw/day to pre-term and low birth weight infants up to 2.5 kg bodyweight.
10 ml/day for all infants and children weighing more than 2.5 kg up to 11 years.

Recommended dosage for children (over 11 years of age), adults and the elderly
It is recommended that the adult preparation Vitlipid N Adult (PL 8828/0124) be used.

Method of administration

For intravenous infusion after dilution, see section 6.6.

4.3 Contraindications

Vitlipid 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 6.3

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 Vitlipid 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. 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 Infant 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamins
ATC code: B05XC

Vitlipid 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 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 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 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 Infant must not be administered undiluted.

Compatibility and instructions for use

All additions should be made aseptically.

Up to 10 ml (1 ampoule) of Vitlipid 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.

Vitlipid 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 Vitlipid N Infant and added to Intralipid 10% or 20%.

For children weighing more than 10 kg Vitlipid 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 Vitlipid 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.

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 08828/0125

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