AUSTRALIAN PRODUCT INFORMATION - VITALIPID® N ADULT and VITALIPID® N INFANT (RETINOL PALMITATE, ERGOCALCIFEROL, DL-ALPHA-TOCOPHEROL, PHYTOMENADIONE)

1 NAME OF MEDICINE

Retinol palmitate (Vitamin A palmitate)

Ergocalciferol (Vitamin D_2)

dl-alpha-tocopherol (Vitamin E)

Phytomenadione (Vitamin K_1)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

10 mL ampoule contains:

	Adult	Infant
Retinol palmitate	1.941 mg	1.353 mg
corresponding to retinol (Vitamin A)	*990 μg (3300 IU)*	*690 μg (2300 IU)*
Ergocalciferol (Vitamin D_2)	5 μg (200 IU)	10 μg (400 IU)
dl-alpha-tocopherol (Vitamin E)	9.1 mg 10 IU)	6.4 mg (7.0 IU)
Phytomenadione (Vitamin K_1)	150 μg	200 μg

Excipients with known effect: Soya oil, Egg lecithin

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Concentrated Emulsion for Injection.

A milky white emulsion. Sterile oil/water emulsion with pH: approx..8 and osmolality: approx. 300 mOsm/kg water.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Vitalipid N Adult is indicated as a supplement in complete intravenous nutrition to meet the daily requirements of the fat-soluble vitamins A, D_2, E and K_1.

Vitalipid N Infant is indicated as a supplement in complete intravenous nutrition to meet the daily requirements of the fat-soluble vitamins A, D_2, E and K_1 in paediatric patients up to 11 years of age.

4.2 Dose and method of administration

Must be diluted before use: Adults and children aged 11 years and above.

Vitalipid N Adult should be added aseptically within one hour of the commencement of the infusion and should be used within 24 hours.

Must be diluted before use: Infants and children under 11 years.
Vitalipid N Infant in a dosage of 1 mL per kg bodyweight per day is added to Intralipid 10% or 20%. The daily dose must not exceed 10 mL. After mixing by gentle agitation the emulsion is infused as described for Intralipid.

Vitalipid N Infant should be added aseptically within one hour of the commencement of the infusion and should be used within 24 hours.

Compatibility
Compatibility of Vitalipid N Adult and Vitalipid N Infant has been demonstrated for use with the named branded products SMOFlipid, Intralipid, Glamin, Dipeptiven, Addaven, Soluvit N (lyophilized) and Glycophos in defined amounts and standard IV solutions of glucose and electrolytes in defined concentrations.

Up to 10 mL (1 ampoule) of Vitalipid N Adult can be added to 500 mL of SMOFlipid. To ensure a homogeneous admixture, the bottle should be inverted several times immediately before the infusion. Vitalipid N Adult up to 10 mL (1 ampoule) can also be added to Intralipid.

Vitalipid N Adult can be used to dissolve Soluvit N. The contents of one vial of Soluvit N is dissolved by the addition of 10 mL of Vitalipid N Adult and added to SMOFlipid or Intralipid.

Vitalipid N Adult is used as an additive to TPN admixtures in compounded bags where data are available and can also be added to the SmofKabiven and Kabiven range of products.

4.3 Contraindications
Vitalipid N is contraindicated in patients with known hypersensitivity to any of the components and a pre-existing hypervitaminosis.
Hypersensitivity to egg-, soya- or peanut protein or to any of the active substances or excipients.
As Vitalipid N is added to Intralipid 10% or 20% before use, it should be noted that Intralipid is contraindicated in patients with acute shock and those with severe disturbances in lipid metabolism such as pathologic hyperlipaemia. Refer to Intralipid Product Information – section 4.3 Contraindications.

4.4 Special warnings and precautions for use
The Vitalipid N doses recommended are insufficient to correct severe deficiency states and may be insufficient in patients with markedly increased requirement.

In patients for whom total parenteral nutrition is continued for prolonged periods, periodic monitoring of blood levels of vitamins, particularly A and D, should be considered.

In patients receiving total parenteral nutrition, routine supplementation with both fat-soluble and water-soluble vitamins is recommended to prevent deficiency states and to obviate the need to speculate on individual vitamin status. However, daily vitamin requirements must be calculated to avoid overdosage and toxic effects, especially with regards to vitamins A and D, and particularly in paediatric patients. Hypervitaminosis A is characterised by fatigue, irritability, anorexia and loss of weight, vomiting and other gastrointestinal disturbances, polyuria and cracking and bleeding lips. Hypervitaminosis D is a metabolic bone disease characterised by hypercalciuria, intermittent hypercalcaemia, osteomalacia and bone pain. Fractures have been reported in patients receiving prolonged parenteral nutrition. This syndrome regressed in some patients after withdrawal of vitamin D supplements.

Fat embolism has been reported as a complication in the rapid infusion of Intralipid. Refer to Intralipid Product Information - Precautions.

This product contains soya oil and egg lecithin which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut.

Use in the elderly
No data available.

Paediatric use
Vitalipid N Infant is indicated in paediatric patients up to 11 years of age.

Effects on laboratory tests
No data available.

4.5 Interaction with other medicines and other forms of interactions
Vitalipid N contains vitamin K_1 which may interact with anticoagulants of the coumarin type.

Interaction with Intralipid; refer to Intralipid Product Information - section 4.4 Special warnings and precautions for use.

Other drugs and solutions should not be added to Vitalipid N when mixed with Intralipid unless specified in section 4.2 dose and method of administration.

4.6 Fertility, pregnancy and lactation
Effects on fertility
No data available.

Use in pregnancy
The recommended Vitalipid N doses may be insufficient in pregnancy and during lactation due to the patient's altered vitamin requirements for example, increased requirements for Vitamin D and E.

Vitalipid N has been administered to pregnant women with no adverse reactions reported.

Use in lactation
No data available.

4.7 Effects on ability to drive and use machines
The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Adverse effects (Undesirable effects)
No adverse effects have been reported with Vitalipid N Adult or Vitalipid N Infant.

Reporting suspected adverse effects
Reporting suspected adverse reactions after registration 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 at https://www.tga.gov.au/reporting-problems.

4.9 Overdose
The possibility of hypervitaminosis A and D should be considered.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia) or 0800 764 766 (New Zealand).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action
No data available.

Clinical trials
No data available.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Genotoxicity
No data available.

Carcinogenicity
No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

10 mL contains:

	Adult	Infant
Excipients		
Soya oil	1 g	1 g
Egg lecithin	120 mg	120 mg
Glycerol	220 mg	220 mg
Sodium hydroxide	to pH 8	to pH 8
Water for injections	to 10 mL	to 10 mL

6.2 Incompatibilities

Vitalipid N may only be added to or mixed with other medicinal products for which compatibility has been documented. For compatibility information, please refer to section 4.2 Dose and method of administration.

6.3 Shelf life

Approved Shelf Life as packaged for sale
2 years

Shelf life after addition or mixing according to directions
Chemical and physical in-use stability of the mixed three chamber bag has been demonstrated for 24 hours at 25°C.

From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C.The resulting solution should be infused within 24 hours and any residue discarded.

6.4 Special precautions for storage

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

For storage conditions after mixing of the medicinal product, refer to section 6.3 Shelf life.

6.5 Nature and contents of container

Infusion concentrate (white emulsion).
10 mL Type I clear glass break-off ampoules.
Ampoules are for single use in one patient only. Discard any residue.

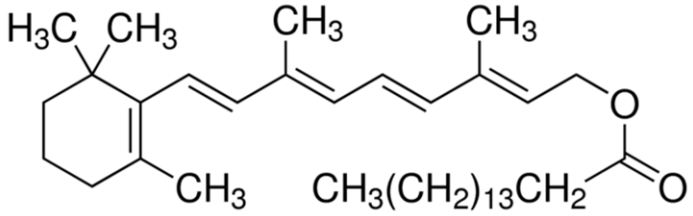
Pack sizes
Vitalipid N Adult: 10 x 10 mL ampoules (AUST R 40252)
Vitalipid N Infant: 10 x 10 mL ampoules (AUST R 40253)

6.6 Special precautions for disposal

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

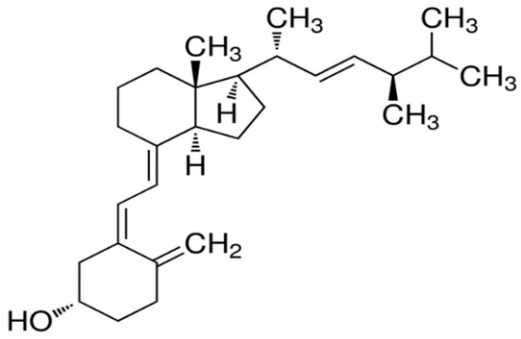
6.7 Physicochemical properties

Chemical structure
Retinol palmitate (Vitamin A)



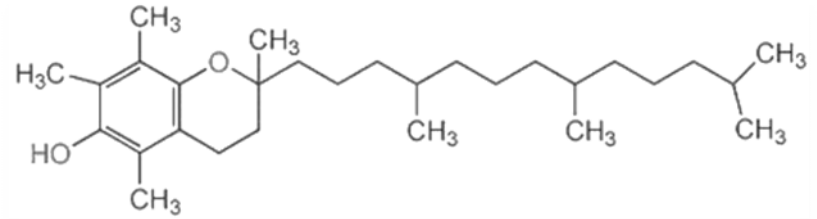
Empirical formula: $C_{36}H_{60}O_2$
Molecular weight: 524.86 g/mol

Ergocalciferol (Vitamin D_2)



Empirical formula: $C_{28}H_{44}O$
Molecular weight: 396.65 g/mol

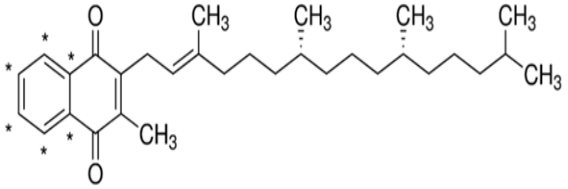
dl-alpha-tocopherol (Vitamin E)



Empirical formula: $C_{29}H_{50}O_2$

Molecular weight: 430.72 g/mol

Phytomenadione (Vitamin K_1)



Empirical formula: $C_{31}H_{46}O_2$
Molecular weight: 450.70 g/mol

CAS number

Active Substance	**CAS number**
Retinol palmitate (Vitamin A palmitate)	79-81-2
Ergocalciferol (Vitamin D_2)	50-14-6
dl-alpha-tocopherol (Vitamin E)	10191-41
Phytomenadione (Vitamin K_1)	84-80-0

7 MEDICINE SCHEDULE (POISONS STANDARD)

Australia: Not Scheduled

8 SPONSOR

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai, NSW 2080
Australia
Telephone: (02) 9391 5555

9 DATE OF FIRST APPROVAL

21 August 1992

10 DATE OF REVISION

01 June 2022

Summary table of changes

Section Changed	**Summary of new information**
2	Changed expression of active ingredient retinol palmitate, removed reference to 1 mL quantities
6	Changed quantities of excipients per 10 mL instead of 1 mL
7, 8	Removed New Zealand details