

1 PRODUCT MEDICINE

Vitalipid® N Adult, concentrated emulsion for injection

Vitalipid® N Infant, concentrated emulsion for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 mL contains:

	<u>Adult</u>	<u>Infant</u>
<u>Active Ingredients</u>		
Retinol palmitate (Vitamin A)	99 µg	69 µg
Ergocalciferol (Vitamin D ₂)	0.5 µg	1.0 µg
dl-alpha-tocopherol (Vitamin E)	0.91 mg	0.64 mg
Phytomenadione (Vitamin K ₁)	15 µg	20 µg

10 mL ampoule contains:

	<u>Adult</u>	<u>Infant</u>
Retinol palmitate (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

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, D₂, E and K₁.

Vitalipid N Infant is indicated as a supplement in complete intravenous nutrition to meet the daily requirements of the fat-soluble vitamins A, D₂, E and K₁ in paediatric patients up to 11 years of age.

4.2 Dose and method of administration

Dose:

Adults and children aged 11 years and above: 10 mL (1 ampoule) per day

Preterm infants and infants with low birth weight (bodyweight < 2.5 kg): 4 mL/kg body weight/day.

Newborns and children with weight over 2.5 kg to children aged up to 11 years: 10 mL (1 ampoule) per day.

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Method of administration

Intravenous administration after aseptic dilution. Must be diluted before use. For instructions on dilution of the medicinal product before administration, please refer to section 6.2 Incompatibilities.

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

Interaction between fat-soluble vitamins and other components in parenteral nutrition products or deliver systems has been rarely reported.

The presence of trace elements may cause slight degradation of Vitamin A. Exposure to ultraviolet light may decompose Vitamin A.

Combination with Warfarin should be avoided as Vitamin K₁ interacts with coumarin-type anticoagulants.

Interaction with Intralipid; refer to Intralipid Product Information – section 4.4.

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

No reproduction studies in animals nor clinical studies in pregnant women have been made. Reports on the safe use of fat-soluble vitamins in pregnant women have been published, therefore Vitalipid Adult can be used during pregnancy. Provided that the dosage recommendations are followed, the safety marginal of Vitalipid Adult should be sufficient for pregnant women. During pregnancy, vitamin A doses higher than 8,000 IU/day (corresponding to 2,400 microg) are contraindicated due to the risk of birth defects.

Use in lactation

Vitalipid Adult may be used during breast-feeding.

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 Undesirable effects

Body System	Frequency	Symptom (s)
Immune system disorders	Not Known. Cannot be estimated from the available data.	Allergic reactions

Reporting suspected adverse effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>

4.9 Overdose

Repeated overdosing with fat-soluble vitamins may lead to toxicity symptoms.

Following prolonged infusion of a too large dose of Vitamin D, serum concentrations of Vitamin D metabolites may be increased. This may cause osteopenia.

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Rapid infusion of Vitamin K1 in a colloid water solution may cause flushing, bronchospasm, tachycardia and hypotension.

Acute overdosing of Vitamin A (doses of more than 150,000 IU) may cause gastrointestinal disorders, headache, increased intracranial pressure, papilledema, psychiatric disorders, irritability, seizures or delayed generalized desquamation of the skin.

Chronic poisoning (prolonged Vitamin A supplement at supraphysiological doses for persons not needing it) may cause increased intracranial pressure, cortical hyperostosis in long bones and premature epiphysis closure. The diagnosis is usually made on presence of tender or painful subcutaneous swelling in the extremities. Periosteal reaction of the elbow bone, the fibula, the clavicle and the ribs is demonstrated radiologically.

Treatment of acute or chronic overdosing

Discontinue the administration of Vitalipid Adult or Vitalipid Infant, reduce the intake of calcium, increase the diuresis (urine excretion), and restore the fluid balance.

For advice on the management of overdose, please contact the National Poisons Centre on 0800 POISON (0800 764 766).

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Blood Substitutes and Perfusion Solutions, I.V. Solution additives, vitamins

ATC code: B05XC

5.1 Pharmacodynamic properties

Mechanism of action

Vitalipid Adult and Vitalipid Infant contain fat-soluble vitamins in amounts that are usually absorbed from ordinary food and it does not have any other pharmacodynamic effects than maintaining or supplementing the nutritional status.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

The fat-soluble vitamins in Vitalipid Adult and Vitalipid Infant are metabolised the same way as the fat-soluble vitamins absorbed from food.

5.3 Preclinical safety data

The safety information of Vitalipid Adult is mainly based on clinical experience.

Genotoxicity

No studies have been performed.

Carcinogenicity

No studies have been performed. The teratogenic effect of Vitamin A in high doses in animals has been well documented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

1 mL contains:

<u>Excipients</u>	<u>Adult</u>	<u>Infant</u>
Soya oil	100 mg	100 mg
Egg lecithin	12 mg	12 mg
Glycerol	22.0 mg	22.0 mg
Sodium hydroxide	to pH 8	to pH 8
Water for injections	to 1 mL	to 1 mL

6.2 Incompatibilities

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.

6.3 Shelf life

Approved Shelf Life as packaged for sale

2 years

Shelf life after addition or mixing according to directions

Although physical and chemical stability of the nominated admixtures of Vitalipid N Adult and Vitalipid N Infant has been demonstrated for 6 days when packed in ethyl-vinyl acetate (EVA) bags stored at 2-8°C followed by one day at 25°C, it is recommended that in order to reduce microbiological contamination hazards, infusion should be commenced as soon as practicable after preparation of the mixture. The resulting solution should be used 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 only.

Pack sizes

Vitalipid N Adult: 10 x 10 mL ampoules

Vitalipid N Infant: 10 x 10 mL ampoules

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6.6 Special precautions for disposal

No special requirements for disposal. Any unused medicine or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE

General Sale Medicine

8 SPONSOR

Fresenius Kabi New Zealand Limited
60 Pavilion Drive
Mangere, Auckland 2022
New Zealand
Freecall: 0800 144 892

9 DATE OF FIRST APPROVAL

08 September 1988

10 DATE OF REVISION OF THE TEXT

16 April 2019

Summary table of changes

Section Changed	Summary of new information
All	Reformat Data Sheet as per new Medsafe requirements
1	Changed names to AAN
2	Changed names to AAN. Excipient information added, other information moved to section 6.1
3	Product description added
4.1	Vitalipid Infant indications re-stated for clarity as previously incomplete
4.2	Dosage and administration amended to remove compatibility information
4.5, 4.6, 4.8, 4.9, 5	Additional details added to align with the SmPC
6.2	New Compatibility information based on studies performed. Aligns with SmPC
6.3	Added shelf life after mixing/addition of additives
6.4	Storage conditions after mixing added, reference to section 6.3
6.5	Details added that 'ampoules are single use'
8	New Zealand sponsor address corrected