

## PRODUCT INFORMATION

### NAME OF MEDICINE

VITALIPID® N INFANT AND ADULT

Multivitamin oily injection

### DESCRIPTION

One mL contains:

	<u>Adult</u>	<u>Infant</u>
Vitamin A (as retinyl palmitate)	99 µg	69 µg
Ergocalciferol	0.5 µg	1.0 µg
dl-α -Tocopherol	0.91 mg	0.64 mg
Phytomenadione	15 µg	20 µg
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

#### Adult

One ampoule contains

Vitamin A	990 µg (3300 IU)
Vitamin D <sub>2</sub>	5 µg (200 IU)
Vitamin E	9.1 mg ( 10 IU)
Vitamin K <sub>1</sub>	150 µg

#### Infant

One mL contains

69 µg (230 IU)
1 µg (40 IU)
0.64 mg ( 0.7 IU)
20 µg

The vitamins are soluble in the oil phase of the emulsion, which has the composition corresponding to that of Intralipid 10%. The daily maintenance dosage of the vitamins A, D<sub>2</sub>, E and K<sub>1</sub> are supplied during intravenous nutrition when:

(i) 10 mL of Vitalipid N Adult are added to 500 mL Intralipid 10% or 20%.

(ii) 1 mL of Vitalipid N Infant per kg bodyweight per day up to a maximum of 10 mL is added to Intralipid 10% or 20%.

### 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<sub>2</sub>, E and K<sub>1</sub>.

As above, Vitalipid N Infant is indicated in paediatric patients up to 11 years of age.

### 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 - Contraindications.

## **PRECAUTIONS**

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 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.

### Interaction with other drugs

Vitalipid N contains vitamin K<sub>1</sub> which may interact with anticoagulants of the coumarin type.

Interaction with Intralipid; refer to Intralipid Product Information - Precautions.

Other drugs and solutions should not be added to Vitalipid N when mixed with Intralipid unless specified in the "Dosage and Administration" section below.

## **ADVERSE EFFECTS**

No adverse effects have been reported with Vitalipid N Adult or Vitalipid N Infant. For admixtures with Soluvit N or Intralipid 10% or 20%, refer to Soluvit and Intralipid Product Informations.

## **DOSAGE AND ADMINISTRATION**

Must be diluted before use: Adults and children aged 11 years and above.  
One ampoule (10 mL) of Vitalipid N Adult is added to 500 mL Intralipid 10% or 20%. After mixing by gentle agitation, the emulsion is infused as described for Intralipid (refer to Intralipid Product Information). The reconstituted Vitalipid N preparation can also be used in All-in-One nutrition (also refer to Intralipid Product Information).

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

Vitalipid N Adult can be used to reconstitute Soluvit N. The contents of one vial of Soluvit N (the daily maintenance dosages of water-soluble vitamins) are dissolved by the aseptic addition of 10 mL of Vitalipid N Adult and added to the Intralipid of the nutritional regimen.

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.

## **OVERDOSAGE**

The possibility of hypervitaminosis A and D should be considered.

## **PRESENTATION AND STORAGE CONDITIONS**

Infusion concentrate (white emulsion).  
10 mL ampoule: box of 10  
Store below 25°C. Protect from light. Do not freeze.

## **NAME AND ADDRESS OF THE SPONSOR**

Fresenius Kabi Australia Pty Limited  
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**POISON SCHEDULE**

Australia: Not Scheduled

New Zealand: General Sale Medicine

**DATE OF TGA APPROVAL:**

25<sup>th</sup> February, 2009

Date of last safety related notification:

19<sup>th</sup> October, 2007

Date of recent amendment:

3<sup>rd</sup> March, 2010