

## ***Vitalipid™ N Infant***

### **Concentrate for solution for infusion**

#### **Presentation**

A white, oil in water emulsion containing the fat-soluble vitamins A, D2, E and K1 in the oil phase of the emulsion with a composition corresponding to that of Intralipid™ 10%.

#### **Declaration**

One ml contains: Retinol. palmit. respond. retinol. 69 µg, calciferol. 1.0 µg, all-rac-alpha- tocopherol. 0.64 mg, phytomenadion. 20 µg, ol. sojae purif. 100 mg, lecithin. purif. e vitello ovi 12 mg, glycerol. anhydrous 22.0 mg, natr. hydroxid. q.s., aq. ad iniectionem. ad 1 ml.

#### **Properties**

Vitalipid N Infant is a sterile emulsion intended for addition to Intralipid.

One ml contains:

|            |         |          |
|------------|---------|----------|
| Vitamin A  | 69 µg   | (230 IU) |
| Vitamin D2 | 1.0 µg  | (40 IU)  |
| Vitamin E  | 0.64 mg | (0,7 IU) |
| Vitamin K1 | 20 µg   |          |

pH approximately 8.

#### **Pharmacodynamics**

Vitalipid N infant is a mixture of fat-soluble vitamins in amounts normally absorbed from the oral diet and should have no pharmacodynamics effect besides maintaining or replenishing the nutritional status.

#### **Pharmacokinetics**

when infused IV, the fat-soluble vitamins in Vitalipid N Infant are metabolized in a similar way to fat-soluble vitamins from an oral diet.

#### **Indications**

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

#### **Contraindications**

Known hypersensitivity to egg-, soya- or peanut protein or to any of the active substances or excipients.

#### **Adverse Reactions**

No adverse effects to Vitalipid N Infant have been reported.

#### **Symptoms and Treatment for Overdosage**

Overdoses of fat-soluble vitamins may lead to toxicity syndromes, but there is no evidence of any toxicity at the dosages recommended. No adverse effects of single overdose of fat-soluble vitamins should occur. No specific treatment is needed. 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 K1 in colloid water solution may provoke flushing, bronchospasm, tachycardia and hypotension. This has not been reported after infusions of Vitalipid N Infant.

#### **Dosage**

Must be diluted before use.

#### ***Preterms and Infants below 2.5kg***

Vitalipid N Infant in a dosage of 4ml/kg bodyweight/day.

***Infants and children above 2.5kg and under 11 years.***

Vitalipid N Infant in a dosage of 10ml/day. The daily dosage must not exceed 10ml. The daily dosage is added to intralipid 10% or 20%.

After mixing by gentle agitation the emulsion is infused as described for Intralipid. The daily maintenance dosages of the vitamins A, D2, E and K1, are thereby supplied.

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

**Warnings and precautions**

Patients known to be allergic to soy and egg proteins should be given Vitalipid N Infant with Caution. Vitalipid N Infant must not be given undiluted.

**Interactions**

Vitalipid N Infant contains Vitamin K1 which may interact with anticoagulants of the coumarin type.

**Storage**

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

**Shelf-Life**

24 months.

**Further Information**

The manufacturer can be consulted for further information on complete and balanced intravenous nutrition regimens.

**Package quantities**

Ampoules 10x10ml

Manufactured by

**Fresenius Kabi AB**, Uppsala, Sweden

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