

Vitalipid™ N Adult

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. 99 µg, calciferol. 0.5 µg, all-rac-alpha-tocopherol. 0.91 mg, phytomenadion. 15 µg, ol. sojae purif. 100 mg, lecithin. purif. e vitello ovi 12 mg, glycerol. anhydr. 22.0 mg, natr. hydroxid. q.s., aq. ad iniectionem. ad 1 ml.

Properties

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

One ampoule contains:

Vitamin A..... 0.99 mg..... (3300 IU)

Vitamin D₂..... 5 µg..... (200 IU)

Vitamin E.....9.1 mg..... (10 IU)

Vitamin K₁..... 150 µg

pH approximately 8.

The daily maintenance dosage of the vitamins A, D₂, E and K₁ are supplied during intravenous nutrition when 10 ml of Vitalipid N Adult are added to 500 ml Intralipid 10% or 20%.

Pharmacodynamics

Not applicable

Pharmacokinetics

When infused intravenously, the fat-soluble vitamins in Vitalipid N Adult are metabolized in a similar way to fat-soluble vitamins from an oral diet.

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.

Contraindications

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

Dosage

Must be diluted before use. Adults and children age 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. The daily maintenance dosage of the vitamins A, D₂, E and K₁ are thereby supplied.

Vitalipid N Adult should be added aseptically within one hour before the start 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 Intralipid.

Warnings and precautions

This medicinal product contains soya-bean oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Vitalipid N Adult must not be given undiluted.

Symptoms and Treatment of Overdose

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 a 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 Adult.

Interactions

Vitalipid N Adult contains vitamin K₁ which may interact with anticoagulants of the coumadin type.

Pregnancy and Lactation

Animal reproduction studies or clinical investigations during pregnancy have not been made with Vitalipid N Adult. There are, however, published reports on safe administration of fat-soluble vitamins in this patient group.

Storage

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

Shelf-life

24 months

Further information

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

Package quantities

Ampoules 10x10 ml

Manufactured by

Fresenius Kabi AB, Uppsala, Sweden

June 2020

