Vitalipid™ N Infant

Concentrate for solution for infusion

Presentation

A white, oil in water emulsion containing the fat-soluble vitamins A, D_2, E and K_1 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 vitelloovi 12 mg, glycerol. anhydrous 22.0 mg, natr.hydroxid. q.s., aq. ad iniect. 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 D_2 1.0 µg (40 IU)

Vitamin E 0.64 mg (0,7 IU)

Vitamin K_1 20 µg

pH approximately 8.

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, D_2, E and K_1.

Contraindications

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

Dosage

Must be diluted before use

Preterms and Infants below 2,5 kg

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

Infants and children above 2,5 kg and under 11 years.

Vitalipid N Infant in a dosage of 10 ml/day. The daily dosage must not exceed 10 ml. 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, D_2, E and K_1 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.

Overdose

In general overdose with Vitalipid N Infant isunlikely to occur. If chronic overdose occurs, the signs would be associated with known symptoms related to an overdose of any of the individual vitamins included in the product.

Chronic overdose of Vitamin A may have adverse effects on the skeleton, skin and central nervous system.

After prolonged infusion of an overdose of Vitamin D , elevated serum concentrations of Vitamin D metabolites may occur. This may cause osteopenia.

There are no known adverse effects of high doses of Vitamin E when administered parenterally.

Rapid infusion of Vitamin K1 in colloid water solution may provoke flushing, bronchospasm, tachycardia, hypotension and even death. This has not been reported after infusions of Vitalipid N Infant, which is in a lipid emulsion.

Treatment should be symptomatic along with the withdrawal of Vitalipid N infant. Spontaneous reversal of any symptoms should occur without requiring a specific antidote.

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 Infant must not be given undiluted.

Interactions

Vitalipid N Infant contains vitamin K_1 which may interact with anticoagulants of the coumarin type.

Storage

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

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

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FRESENIUS KABI

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