PACKAGE INSERT

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

VITALIPID® NOVUM INFANT Concentrate (for solution) for infusion

COMPOSITION

Each 1 ml contains:

Retinol palmitate corresponding to

Retinol (Vitamin A)	69 µg (230 IU)
Ergocalciferol (Vitamin D_2)	1,0 µg (40 IU)
dl-α-Tocopherol (Vitamin E)	0,64 mg (0,7 IU)
Phytomenadione (Vitamin K_1)	20 µg

Other ingredients:

Purified soybean oil

Purified egg phospholipids

Glycerol

Sodium hydroxide

Water for injection

PHARMACOLOGICAL CLASSIFICATION

A 22.1 Vitamins – other

PHARMACOLOGICAL ACTION

Vitalipid® Novum Infant is a formulation of fat soluble vitamins.

INDICATIONS

Vitalipid® Novum Infant is indicated as a supplement in complete intravenous nutrition to meet the daily requirements of the fat soluble vitamins A, D_2, E and K_1 in infants and children under 11 years of age.

Vitalipid® Novum Infant should be added to Intralipid® 10 % or 20 % before use.

CONTRA-INDICATIONS

Hypersensitivity to any of the ingredients.

Patients known to be allergic to soy, egg or peanut proteins.

WARNINGS AND SPECIAL PRECAUTIONS

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

Vitalipid® Novum Infant must not be given undiluted.

The intake of more than 8 000 IU of vitamin A is not recommended during pregnancy due to the risk of birth defects.

Rapid infusion of vitamin K_1 in colloid water solution may provoke flushing, bronchospasm, tachycardia and hypotension. This has not been reported after infusions of Vitalipid® Novum Infant.

Cross allergic reaction has been observed between soy-bean and peanut.

Caution should be exercised in the administration of Vitalipid® Novum Infant in renal failure.

INTERACTIONS

The presence of trace elements may cause some degradation of vitamin A.

Retinol (vitamin A) may be broken down by exposure to ultraviolet light.

Vitamin K_1 interacts with anticoagulants of the coumarin type.

DOSAGE AND DIRECTIONS FOR USE

Vitalipid® Novum Infant must be diluted before use.

All additions should be made aseptically.

For infants and children under eleven years a dosage of 1 ml per kg body weight per day is added to Intralipid® 10 % or 20 %. The daily dosage must not exceed 10 ml. After mixing by gentle agitation the emulsion is infused as directed for Intralipid®.

For children with a body weight of more than 10 kg, Vitalipid® Novum Infant (10 ml) can also be used to dissolve one vial of Soluvit® Novum and added to Intralipid®.

For children with a body weight less than 10 kg the dissolution of Soluvit® Novum is not recommended due to differences in dosage regimens for Vitalipid® Novum Infant and Soluvit® Novum. Instead, one vial of Soluvit® Novum can be dissolved in 10 ml of Intralipid® or water for injection and added separately to Intralipid®.

Stability:

The addition of Vitalipid® Novum Infant to Intralipid® 10 % or 20 % should be made aseptically within one hour before the start of the infusion, and the infusion should be completed within 24 hours from preparation to prevent microbiological contamination. The left-over contents of opened bottles/vials/ampoules should be discarded and not kept for later use.

Vitalipid® Novum Infant may not be added to products other than Intralipid® unless compatibility has been documented.

SIDE EFFECTS

Refer to "Warnings and special precautions".

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

After several weeks infusion of too large doses elevated serum concentrations of vitamin D metabolites may occur. This may aggravate osteopenia in premature infants.

IDENTIFICATION

A white emulsion

PRESENTATION

10 ml clear glass ampoules in boxes of 10.

STORAGE INSTRUCTIONS

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

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER

30/22.1/0201

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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