SCHEDULING STATUS

S3

PROPRIETARY NAME (AND DOSAGE FORM)

VITALIPID® NOVUM ADULT (Concentrate (for solution) for infusion)

COMPOSITION

Each 1 ml contains:

Retinol palmitate corresponding to	
Retinol (Vitamin A)	99 µg (330 IU)
Ergocalciferol (Vitamin D_2)	0,5 µg (20 IU)
dl-α-Tocopherol (Vitamin E)	0,91 mg (1 IU)
Phytomenadione (Vitamin K_1)	15 µg

Other ingredients:

Purified soybean oil

Purified egg phospholipids

Glycerol

Sodium hydroxide

Water for injection

PHARMACOLOGICAL CLASSIFICATION

A 22.1 Vitamins - other

PHARMACOLOGICAL ACTION

Pharmacodynamic properties:

Vitalipid® Novum Adult is a mixture of fat-soluble vitamins in amounts normally absorbed from the diet and should have no pharmacodynamic effect apart from maintaining the nutritional status.

Pharmacokinetic properties:

When infused intravenously, the fat-soluble vitamins in Vitalipid® Novum Adult are metabolised in a way similar to fat-soluble vitamins from the diet.

INDICATIONS

Vitalipid® Novum Adult is indicated in adult patients and children from 11 years of age (average body weight of 36 kg) as a supplement in complete intravenous nutrition to meet the daily requirements of the fat-soluble vitamins A, D_2, E and K_1.

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 Adult contains vitamin K_1 which may interact with anticoagulants of the coumarin type.

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

Vitalipid® Novum Adult must not be given undiluted.

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 Adult.

Cross allergic reaction has been observed between soybean and peanut.

Caution should be exercised in the administration of Vitalipid® Novum Adult 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 Adult must be diluted before use.

For adults and children age eleven years and above (average body weight of 36 kg), one ampoule of Vitalipid® Novum Adult is added to 500 ml Intralipid® 20 % or 10 %. After mixing by gentle agitation the emulsion is infused as directed for Intralipid®. Other products recommended for admixing are Vitrimix® and Structolipid®.

The daily maintenance doses of vitamin A, D_2, E and K_1 are supplied during intravenous nutrition when 10 ml Vitalipid® Novum Adult is added to the nutrition regimen.

Vitalipid® Novum Adult should be added aseptically within one hour before the start of the infusion and should be used 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 Adult can be used to reconstitute Soluvit® Novum. The contents of one vial of Soluvit® Novum (the daily maintenance dosages of water-soluble vitamins) are dissolved by the aseptic addition of Vitalipid® Novum Adult and added to the Intralipid®, Vitrimix® or Structolipid® of the nutritional regimen.

SIDE EFFECTS

See "Contra-indications" and "Warnings and special precautions".

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Overdoses of fat-soluble vitamins may lead to toxicity syndromes, but there is no evidence of any toxicity at the dosages recommended.

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

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

Z/22.1/236

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

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