PATIENT INFORMATION LEAFLET

Scheduling status: S3

Vitalipid® Novum Infant, Concentrate (for solution) for infusion

Vitamin A, D_2, E and K_1 in an emulsion

Read all of this leaflet carefully before you start using Vitalipid Novum Infant

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Vitalipid Novum Infant has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as those of yours.

WHAT VITALIPID® NOVUM INFANT CONTAINS

The active ingredients are:

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

The other ingredients are purified soybean oil, purified egg phospholipids, glycerol, sodium hydroxide and water for injection.

WHAT VITALIPID® NOVUM INFANT IS USED FOR

Vitalipid® Novum Infant is used in infants and children under 11 years of age (average body weight of 36 kg) as a supplement in complete intravenous nutrition. The solution meets the daily requirements of the fat soluble vitamins A, D_2, E and K_1.

BEFORE YOU RECEIVE VITALIPID® NOVUM INFANT

You should not be given Vitalipid® Novum Infant if:

- you are hypersensitive to any of the ingredients of Vitalipid Novum Infant
- you are allergic to soy, egg or peanut proteins. Cross allergic reactions can occur between soybean and peanut

Take special care with Vitalipid® Novum Infant if:

- you are taking anticoagulants of the coumarin type, as these may interact with vitamin K_1
- you are pregnant due to the risk of birth defects when taking more than 8 000 IU of vitamin A
- you are taking trace elements as these may cause some degradation of vitamin A
- you have renal failure

Pregnancy and breastfeeding

If you are pregnant or breast feeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before receiving Vitalipid Novum Infant.

Driving and using machinery

After receiving Vitalipid® Novum Infant, your ability to drive or operate machinery will not be affected

Taking other medicines with Vitalipid® Novum Infant

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Take special care if you are taking anticoagulants of the coumarin type as interactions may occur with vitamin K_1.

Vitalipid® Novum Infant may not be diluted with, or added to, any other product not specifically mentioned in this leaflet.

HOW VITALIPID® NOVUM INFANT IS ADMINISTERED

You will not be expected to give yourself Vitalipid Novum Infant. It will be given to you by a person who is qualified to do so.

Vitalipid Novum Infant will be given under close supervision of your doctor and he/she will closely control the amount you receive.

Mode of administration

Vitalipid® Novum Infant must be diluted before use. It may not be added to products other than Intralipid® unless compatibility has been documented. All additions must be made aseptically.

Dosage

For infants and children under 11 years of age (average body weight of 36 kg), a dosage of 1 ml per kg body weight per day is added to Intralipid®10 % or 20 %. The

daily dose must not exceed 10 ml. After mixing by gentle agitation the emulsion is infused as directed for Intralipid®.

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.

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 the dosage regimens for Vitalipid® Novum Infant and Soluvit Novum. Instead, Soluvit Novum can be dissolved in 10 ml of Intralipid® or water for injection and added separately to Intralipid®.

If you received more Vitalipid® Novum Infant than you should:

Since a healthcare professional will administer Vitalipid Novum Infant, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If you receive a large dose over several weeks, the concentration of Vitamin D metabolites in the blood may become higher. This may aggravate osteopenia (decrease in the bone mass) in premature infants.

POSSIBLE SIDE EFFECTS

Vitalipid Novum Infant can have side effects.

See “You should not be given Vitalipid Novum Infant”.

Not all side effects reported for Vitalipid Novum Infant are included in this leaflet. Should your general health worsen or if you experience any untoward effects while

receiving Vitalipid Novum Infant, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF VITALIPID® NOVUM INFANT

Store all medicines out of reach of children.

Store at or below 25 ºC.

Protect from light. Vitamin A may be broken down by exposure to ultraviolet light.

Vitalipid® Novum Infant should be used within 24 hours after being mixed for an infusion.

The left-over contents of opened ampoules should be discarded and not kept for later use.

PRESENTATION OF VITALIPID® NOVUM INFANT

It is presented in a 10 ml clear glass ampoule, in boxes of 10.

IDENTIFICATION OF VITALIPID® NOVUM INFANT

Vitalipid® Novum Infant is a white emulsion.

REGISTRATION NUMBER

30/22.1/0201

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER

Fresenius Kabi South Africa (Pty) Limited , Stand 7 Growthpoint Park, 2 Tonetti Street, Halfway House, 1685

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