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FRESENIUS KABI

SCHEDULING STATUS S3

PROPRIETARY NAME AND DOSAGE FORM cbg/008/08/15

Vitalipid® Novum Infant

Sterile emulsion for i.v. infusion

337 167

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
Contains sugar (as Glycerol 22,0 mg)

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 OVER-DOSAGE 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
FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Stand 7, Growthpoint Park
2 Tonetti Street
Midrand, 1682
South Africa
Telephone no.: +27 (0)11 545 0000

Manufacturer:
Fresenius Kabi AB, Rapsgatan 7, SE-751 74, Uppsala, Sweden

DATE OF PUBLICATION OF THIS PACKAGE INSERT
Date of registration: 9 December 2008

Prescription only medicine (POM)
Namibia NS2 04/22.1/1051

PATIENT INFORMATION LEAFLET

Scheduling status: S3

Vitalipid® Novum Infant

Sterile emulsion for i.v. 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 D2)	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.
Contains sugar (as Glycerol 22,0 mg).

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 °C.
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) Ltd, Stand 7 Growthpoint Park, 2 Tonetti Street, Midrand, 1682 South Africa
Telephone no.: +27 (0)11 545 0000

DATE OF PUBLICATION
9 December 2008

Prescription only medicine (POM)
Namibia NS2 04/22.1/1051

INLIGTINGSPAMFLET VIR DIE PASIËNT

SKEDULERINGSTATUS: S3

Vitalipid® Novum Infant

Steriel emulsie vir i.v infusie

Vitamien A, D_2, E en K_1 in 'n emulsie

Lees die hele pamflet deeglik deur voordat jy begin om Vitalipid Novum Infant te gebruik.
- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil lees.
- Indien jy verdere vrae het, raadpleeg asseblief jou dokter of apteker.
- Vitalipid Novum Infant is jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

WAT VITALIPID® NOVUM INFANT BEVAT

Die aktiewe bestanddele is:

Retinolpalmitaat ooreenstemmend met	
Retinol (Vitamien A)	69 µg (230 IE)
Ergokalsiferol (Vitamien D_2)	1,0 µg (40 IE)
dl-α-Tokoferol (Vitamien E)	0,64 mg (0,7 IE)
Fitomenadioon (Vitamien K_1)	20 µg

Die ander bestanddele is gesuiwerde sojaboonolie, gesuiwerde eiergeelfosfolipiede, gliserol, natriumhidroksied en water vir inspuiting. Bevat suiker (as Gliserol 22,0 mg).

WAAROOR VITALIPID NOVUM INFANT GEBRUIK WORD

Vitalipid® Novum Infant word gebruik by volwassenes en kinders ouer as 11 jaar (gemiddelde liggaamsgewig 36 kg) as 'n byvoeging in algehele intraveneuse voeding. Die oplossing voldoen aan die daaglikse behoeftes aan die vetoplosbare vitamiene A, D_2, E en K_1.

VOORDAT JY VITALIPID® NOVUM INFANT ONTVANG

Vitalipid® Novum Infant moet nie aan jou gegee word nie as:
- jy allergies is vir enige van die bestanddele van Vitalipid Novum Infant
- jy allergies is vir soja-, eier- of grondboontjieproteïene. Kruisallergiese reaksies tussen sojaboon- en grondboontjieprodukte kan voorkom

Wees versigtig met Vitalipid® Novum Infant as:
- jy antistolmiddels (bloedverdunners) van die kumarientipe, soos warfarien, neem, want dit kan 'n interaksie met vitamien K_1 hê
- jy swanger is nie, as gevolg van die risiko vir geboorte-afwykings as jy meer as 8 000 IE vitamien A neem
- jy spoorelemente neem, want dit kan 'n mate van afbraak van Vitamien A veroorsaak
- jy nierversaking het

Swangerskap en borsvoeding
Indien jy swanger is, of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgkundige voordat jy Vitalipid Novum Infant ontvang.

Bestuur en gebruik van masjinerie
Nadat jy Vitalipid Novum Infant® ontvang het, sal jou vermoë om te bestuur of masjinerie te hanteer nie aangetas wees nie.

Die gebruik van ander medisynes saam met Vitalipid® Novum Infant
Lig altyd jou professionele gesondheidsorgkundige in as jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Wees veral versigtig as jy antistolmiddels van die kumarientipe neem, want interaksies kan met vitamien K_1 voorkom.
Vitalipid® Novum Infant kan nie verdun word met, of gevoeg word by enige ander produk wat nie spesifiek in hierdie pamflet vermeld word nie.

HOE VITALIPID® NOVUM INFANT TOEGEDIEN WORD

Daar sal nie van jou verwag word om Vitalipid Novum Infant aan jouself toe te dien nie. Dit sal aan jou toegedien word deur 'n persoon wat gekwalifiseer is om dit te doen.
Vitalipid Novum Infant sal onder direkte toesig van jou dokter gegee word en hy/sy sal die hoeveelheid wat jy ontvang noukeurig beheer.

Metode van toediening
Vitalipid® Novum Infant moet voor gebruik verdun word. Dit mag nie by ander produkte as Intralipid® gevoeg word nie, tensy verenigbaarheid bepaal is. Alle byvoegings moet asepties gedoen word.

Dosis
Vir babas en kinders jonger as 11 jaar (gemiddelde liggaamsgewig 36 kg) word 'n dosis van 1 ml per kg liggaamsmassa per dag by Intralipid® 10 % of 20 % gevoeg. Die daaglikse dosis moet nie 10 ml oorskry nie. Na vermenging deur ligte skommeling word die emulsie soos aangedui vir Intralipid® geïnfuseer.
Die byvoeging van Vitalipid® Novum Infant by Intralipid® 10 % of 20 % moet binne een uur voor aanvang van die infusie asepties gedoen word, en die infusie moet binne 24 uur na voorbereiding voltooi word.
Vir kinders met 'n liggaamsmassa van meer as 10 kg, kan Vitalipid® Novum Infant (10 ml) ook gebruik word om een flessie Soluvit Novum op te los, en dan by Intralipid® gevoeg word.
Vir kinders met 'n liggaamsmassa van minder as 10 kg, word die oplossing van Soluvit Novum nie aanbeveel nie, weens die verskille in dosisregimens vir Vitalipid® Novum Infant en Soluvit Novum. Pleks daarvan kan Soluvit Novum in 10 ml Intralipid® of water vir inspuiting opgelos word en apart by Intralipid® gevoeg word.

Indien jy meer Vitalipid Novum Infant ontvang het as wat jy moes:
Aangesien 'n professionele gesondheidsorgkundige Vitalipid Novum Infant sal toedien, sal hy/sy die dosis beheer. In geval van oordosering sal jou dokter egter die oordosering behandel.
Indien jy 'n hoë dosis oor etlike weke ontvang, kan die konsentrasie van vitamien-D metaboliete in die bloed hoër word. Dit kan osteopenie (afname in beenmassa) by vroeggebore babas veroorsaak.

MOONTLIKE NEWE-EFFEKTE

Vitalipid Novum Infant kan newe-effekte hê.
Kyk "Vitalipid Novum Infant moet nie aan jou gegee word nie".
Nie alle newe-effekte wat vir Vitalipid Novum Infant aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid agteruitgaan of jy enige ongunstige effekte ervaar terwyl jy Vitalipid Novum Infant ontvang, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgwerker.
Indien jy enige newe-effekte waarneem wat nie in hierdie pamflet vermeld word nie, lig asseblief jou dokter of apteker in.

BERGING EN WEGDOENING VAN VITALIPID NOVUM INFANT

Bêre alle medisyne buite bereik van kinders.
Bewaar by of onder 25 °C.
Beskerm teen lig. Vitamien A kan deur blootstelling aan ultraviolet lig afgebreek word.
Vitalipid® Novum Infant moet gebruik word binne 24 uur nadat dit gemeng is vir 'n infusie.
Die oorskiet van die oopgemaakte ampulle moet weggegooi word en nie vir latere gebruik gebêre word nie.

AANBIEDING VAN VITALIPID® NOVUM INFANT

Dit word aangebied in 'n 10 ml helder glasampul, in kartonne met 10.

IDENTIFIKASIE VAN VITALIPID® NOVUM INFANT

Vitalipid® Novum Infant is 'n wit emulsie.

REGISTRASIENOMMER

30/22.1/0201

NAAM EN BESIGHEIDSADRES VAN DIE REGISTRASIEHOUER

Fresenius Kabi South Africa (Pty) Ltd, Stand 7, Growthpoint Park, Tonettistraat 2, Midrand, 1682 South Africa
Telephone no.: +27 (0)11 545 0000

DATUM VAN PUBLIKASIE

Datum van registrasie: 9 Desember 2008

FRESENIUS KABI