337 165 (replace 336 304)

Tryckspecifikation

Format:	296,3 x 210 mm
Color:	Black
Fontsize:	8 pt

4:e korr 2018-03-20
Niklas Baudin
+46 18 64 43 69

Kodens skalning 200%

FRESENIUS KABI

SCHEDULING STATUS S3

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

Vitalipid® Novum Adult

Sterile emulsion of i.v. infusion

337 165

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
Contains sugar (as Glycerol 22,0 mg)

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 OVER-DOSAGE 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
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
25 November 2011

Prescription only medicine (POM)
Namibia: NS2 04/22.1/1038
Kenya: H2010/20622/814, POM
Zambia: 254/043, POM

PATIENT INFORMATION LEAFLET

Scheduling status: S3

Vitalipid® Novum Adult

Sterile emulsion of i.v. infusion

Vitamin A, D_2, E and K_1 in an emulsion

Read all of this leaflet carefully before you receive Vitalipid Novum Adult
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Vitalipid Novum Adult 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 yours.

1. WHAT VITALIPID NOVUM ADULT CONTAINS
The active ingredients are:
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

The other ingredients are purified soybean oil, purified egg phospholipids, glycerol, sodium hydroxide and water for injection. Contains sugar (as Glycerol 22,0 mg).

2. WHAT VITALIPID NOVUM ADULT IS USED FOR
Vitalipid Novum Adult is used in adults and children from 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.

3. BEFORE YOU RECEIVE VITALIPID NOVUM ADULT
You should not receive Vitalipid Novum Adult if:
- you are hypersensitive to any of the ingredients of Vitalipid Novum Adult
- you are allergic to soy, egg or peanut proteins. Cross allergic reactions can occur between soya-bean and peanut products.

Take special care with Vitalipid Novum Adult if:
- you are taking anticoagulants (blood thinners) such as warfarin, as these may interact with vitamin K1
- 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 kidney failure

Pregnancy and breastfeeding
If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before receiving Vitalipid Novum Adult.

Driving and using machinery
After receiving Vitalipid Novum Adult, your ability to drive or operate machinery will not be affected.

Taking other medicines with Vitalipid Novum Adult
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 (blood thinners) such as warfarin, as interactions may occur with vitamin K_1.
Vitalipid Novum Adult may not be diluted with, or added to, any other product not specifically mentioned in this leaflet.

4. HOW VITALIPID NOVUM ADULT IS ADMINISTERED
You will not be expected to give yourself Vitalipid Novum Adult. It will be given to you by a person who is qualified to do so.
Vitalipid Novum Adult will be given under close supervision of your doctor and the amount you receive will be controlled.

Mode of administration
Vitalipid Novum Adult must be diluted before use.

For adults and children age 11 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. Vitrimix and Structolipid may also be used for dilution.
Vitalipid Novum Adult should be added in a germ-free environment within one hour of the start of the infusion, and should be used within 24 hours.
Vitalipid Novum Adult can be used to reconstitute Soluvit Novum, which contains the water soluble vitamins. The contents of one vial of Soluvit Novum is dissolved in a germ-free environment in Vitalipid Novum Adult, and added to Intralipid, Vitrimix or Structolipid.

Dosage
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 plan.

If you received more Vitalipid Novum Adult than you should:
Since a healthcare professional will administer Vitalipid Novum Adult, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

Receiving too much of the fat soluble vitamins found in Vitalipid Novum Adult may lead to symptoms of toxicity. However, there is no evidence of toxicity occurring with Vitalipid Novum Adult at the dosages recommended.

If you receive a prolonged infusion of an overdose, the concentration of vitamin D metabolites in the blood may become higher. This may cause osteopenia (decrease in the bone mass).

5. POSSIBLE SIDE EFFECTS
Vitalipid Novum Adult may have side effects.
See "You should not receive Vitalipid Novum Adult".
Not all side effects reported for Vitalipid Novum Adult are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Vitalipid Novum Adult, 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.

6. STORING AND DISPOSING OF VITALIPID NOVUM ADULT
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 Adult 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.

7. PRESENTATION OF VITALIPID NOVUM ADULT
It is presented in a 10 ml clear glass ampoule, in boxes of 10.

8. IDENTIFICATION OF VITALIPID NOVUM ADULT
Vitalipid Novum Adult is a white emulsion.

9. REGISTRATION NUMBER
Z/22.1/236

10. NAME AND ADDRESS OF REGISTRATION HOLDER
Fresenius Kabi South Africa (Pty) Ltd
Stand 7, Growthpoint Park, Tonetti Street, Midrand,1682 South Africa
Telephone no.: +27 (0)11 545 0000

11. DATE OF PUBLICATION
25 November 2011

SKEDULERINGSTATUS S3

HANDELSNAAM EN DOSEERVORM

Vitalipid® Novum Adult

Steriel emulsie vir i.v infusie

Vitalipid Novum Adult (Konsentraat (vir oplossing) vir infusie)
Vitamien A, D_2, E en K_1 in 'n emulsie

Lees die hele pamflet deeglik deur voordat jy Vitalipid Novum Adult ontvang
- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil lees.
- Indien jy nog vrae het, raadpleeg asseblief jou dokter of apteker.
- Vitalipid Novum Adult is vir 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.

1. WAT VITALIPID NOVUM ADULT BEVAT

Die aktiewe bestanddele is:
Retinolpalmitaat ooreenstemmend met

Retinol (Vitamien A)	99 µg (330 IE)
Ergokalsiferol (Vitamien D_2)	0,5 µg (20 IE)
dl-α-Tokoferol (Vitamien E)	0,91 mg (1 IE)
Fitomenadioon (Vitamien K_1)	15 µg

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

2. WAARVOOR VITALIPID NOVUM ADULT GEBRUIK WORD

Vitalipid® Novum Adult 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.

3. VOORDAT JY VITALIPID NOVUM ADULT ONTVANG

Jy moet nie Vitalipid Novum Adult ontvang nie, as:
- jy allergies is vir enige van die bestanddele van Vitalipid Novum Adult
- jy allergies is vir soja-, eier- of grondboontjieproteïene. Kruisallergiese eaksies tussen sojaboon- en grondboontjieprodukte kan voorkom.

Wees versigtig met Vitalipid Novum Adult as:
- jy antistolmiddels (bloedverdunners) soos warfarien neem, want dit kan 'n interaksie met vitamien K1 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 Adult ontvang.

Bestuur en gebruik van masjinerie
Nadat jy Vitalipid Novum Adult 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 Adult
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 (bloedverdunners) soos warfarien neem, want dit kan 'n interaksie met vitamien K_1 hê.
Vitalipid Novum Adult kan nie verdun word met, of gevoeg word tot, enige ander produk wat nie spesifiek in hierdie pamflet vermeld word nie.

4. HOE VITALIPID NOVUM ADULT TOEGEDIEN WORD

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

Metode van toediening
Vitalipid Novum Adult moet voor gebruik verdun word.

Vir volwassenes en kinders elf jaar en ouer (gemiddelde liggaamsgewig 36 kg) word een ampul Vitalipid Novum Adult by 500 ml Intralipid 20 % of 10 % gevoeg. Nadat dit liggies geskommel is, word die emulsie ingedrup, soos aangewys vir Intralipid. Vitrimix en Structolipid kan ook vir verdunning gebruik word.
Vitalipid Novum Adult moet in 'n kiemvrye omgewing bygevoeg word, binne een uur van die begin van die infusie en moet binne 24 uur gebruik word.
Vitalipid Novum Adult kan gebruik word vir hersamestelling van Soluvit Novum, wat die wateroplosbare vitamiene bevat. Die inhoud van een flessie Soluvit Novum word in 'n kiemvrye omgewing in Vitalipid Novum Adult opgelos en gevoeg by Intralipid, Vitrimix of Structolipid.

Dosis
Die daaglikse onderhoudsdosis van vitamiene A, D_2, E en K_1 word voorsien tydens aarvoeding wanneer 10 ml Vitalipid Novum Adult gevoeg word tot die voedingsplan.

Indien jy meer Vitalipid Novum Adult ontvang het as wat jy moes:
Aangesien 'n professionele gesondheidsorgkundige Vitalipid Novum Adult sal toedien, sal hy/sy die dosis beheer. Ingeval daar egter 'n oordosering is, sal jou dokter die oordosering hanteer.
Indien daar te veel van die vetoplosbare vitamiene wat in Vitalipid Novum Adult aanwesig is, toegedien word, kan dit lei tot simptome van toksisiteit. Daar is egter geen bewys van toksisiteit met Vitalipid Novum Adult by die aanbevole doserings nie.
Indien jy 'n langdurige infusie van 'n oordosering ontvang, kan die konsentrasie van vitamien-D metaboliete in die bloed hoër word. Dit kan osteopenie (afname in beenmassa) veroorsaak.

5. MOONTLIKE NEWE-EFFEKTE

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

6. BERGING EN WEGDOENING VAN VITALIPID NOVUM ADULT

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 Adult 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.

7. AANBIEDING VAN VITALIPID NOVUM ADULT

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

8. IDENTIFIKASIE VAN VITALIPID NOVUM ADULT

Vitalipid Novum Adult is 'n wit emulsie.

9. REGISTRASIENOMMER

Z/22.1/236

10. NAAM EN ADRES 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

11. DATUM VAN PUBLIKASIE

25 November 2011

FRESENIUS KABI