APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Vitalipid Novum Adult (Concentrate (for solution) for 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.

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 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 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 [~~BUSINESS~~] ADDRESS OF REGISTRATION HOLDER

Fresenius Kabi South Africa (Pty) Limited

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11. DATE OF PUBLICATION

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