Vitalipid® N Infant & Vitalipid® N Adult

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.
Note: Vitalipid® N Infant & Vitalipid® N Adult will be referred as 'Vitalipid N' throughout the CMI.

1. Why am I using Vitalipid N?

Vitalipid N is a sterile emulsion supplement which provides the body with fat-soluble multivitamins by the intravenous route. Vitalipid N contains the active ingredients retinol palmitate (Vitamin A palmitate), ergocalciferol (Vitamin D_2), dl-alpha-tocopherol (Vitamin E) and phytomenadione (Vitamin K_1).

For more information, see Section 1. Why am I using Vitalipid N? in the full CMI.

2. What should I know before I use Vitalipid N?

Do not use if you or your child have an allergy to soya oil, eggs, peanuts or are allergic to the active ingredients or any of the ingredients listed at the end of this leaflet. Do not use if you or your child have very high levels of vitamins in your system, have a sudden, dangerous drop in your blood pressure or have an inability to break down fats.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Vitalipid N? in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Vitalipid N and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Vitalipid N?

The dose of Vitalipid N which you will require will be determined by your doctor or pharmacist. The doctor will supervise your treatment or your child's treatment with Vitalipid N.

More instructions can be found in Section 4. How do I use Vitalipid N? in the full CMI.

5. What should I know while using Vitalipid N?

Things you should do	• Remind any doctor, dentist, pharmacist or nurse treating you that you are using VItalipid N • Call you doctor straightaway if you have signs and symptoms of allergic reactions. In case of an allergic reaction, the infusion should be stopped immediately, and appropriate measures need to be taken.
Things you should not do	• Do not stop using this medicine without consulting your health care professional • Do not take any other medicines without first telling your health care professional • Do not give this medicine to anyone else, even if they have the same condition as you
Driving or using machines	• The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.
Drinking alcohol	• The effects of alcohol with Vitalipid N use were not studied. Your doctor will decide what you need to do.
Looking after your medicine	• Store below 25°C. Protect from light and do not freeze. Do not use after the expiry date stated on the label.

For more information, see Section 5. What should I know while using Vitalipid N? in the full CMI.

6. Are there any side effects?

No side effects have been reported with Vitalipid N. If you get any adverse effects, talk to your doctor or nurse.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Vitalipid® N Infant & Vitalipid® N Adult

Active ingredients: *retinol palmitate (Vitamin A palmitate), ergocalciferol (Vitamin D_2), dl-alpha-tocopherol (Vitamin E) and phytomenadione (Vitamin K_1).*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Vitalipid N. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Vitalipid N.**

Where to find information in this leaflet:

1. Why am I using Vitalipid N?
2. What should I know before I use Vitalipid N?
3. What if I am taking other medicines?
4. How do I use Vitalipid N?
5. What should I know while using Vitalipid N?
6. Are there any side effects?
7. Product details

1. Why am I using Vitalipid N?

Vitalipid N contains the active ingredients retinol palmitate (Vitamin A palmitate), ergocalciferol (Vitamin D_2), dl-alpha-tocopherol (Vitamin E) and phytomenadione (Vitamin K_1).

Vitalipid N is a sterile supplement emulsion which provides the body with fat-soluble multivitamins via intravenous route. Intravenous nutrients and supplement can be given when the intake of nutrients or food into the mouth or directly into the gut is not possible or not enough to supply the body's needs. Vitamins supplementation is especially important during physical stress from illness or recent surgery.

Vitalipid N Adult is intended as a supplement in complete intravenous nutrition to meet the daily requirements of the fat-soluble vitamins A, D_2, E and K_1.

Vitalipid N Infant is intended 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 paediatric patients up to 11 years of age.

2. What should I know before I use Vitalipid N?

Warnings

Do not use Vitalipid N if you or your child:

- are allergic to the active ingredients or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- have very high levels of vitamins in your system.
- have a sudden, dangerous drop in your blood pressure.
- have an inability to break down fats.

Check with your doctor if you or your child:

- have liver or kidney disease
- are taking anticoagulants (medicines for preventing blood clotting)
- are allergic to soya-, egg- or peanut protein or any other medicines or any other substances, such as foods, preservatives or dyes
- are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop. These medicines may affect the action of Vitalipid N or may affect how well Vitalipid N works.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

The recommended Vitalipid N doses may be insufficient in pregnancy and during lactation due to the patient's altered vitamin requirements for example, increased requirements for Vitamin D and E.

Vitalipid N has been administered to pregnant women with no adverse reactions reported.

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use in elderly

No data is available for use of Vitalipid N in elderly patients. Your doctor will decide what to do.

Use in Paediatrics

Vitalipid N Infant is indicated in paediatric patients up to 11 years of age.

3. What if I am taking other medicines?

Some medicines may interfere with Vitalipid N and affect how it works.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Vitalipid N.

4. How do I use Vitalipid N?

How much is given

The dose of Vitalipid N which you will require will be determined by your doctor or pharmacist.

How to take Vitalipid N

- Vitalipid N will be given to you under supervision by a health care professional.
- Vitalipid N is usually mixed in a bottle or a bag of lipid, amino acids, glucose and other standard intravenous solutions, alone or together with water-soluble vitamins and given as a continuous infusion into a vein. An electronic pump may be used to control the speed of the infusion of drip.
- For single use and for one person only. Any unused portion must be discarded.

If you forget to use Vitalipid N

This rarely happens as Vitalipid N is usually administered under the care of a trained health care professional in a hospital or clinic setting.

If you use too much Vitalipid N

This rarely happens as Vitalipid N is usually administered under the care of a trained professional in a hospital or clinic setting. However, if you or your child is given too much of Vitalipid N, you or your child may experience a condition of high levels of vitamins in your system.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

If you think that you have used too much Vitalipid N, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Vitalipid N?

Things you should do

- Remind any doctor, dentist, pharmacist or nurse treating you that you are using VItalipid N.

Call your doctor straight away if you:

- have signs and symptoms of allergic reactions. In case of an allergic reaction, the infusion should be stopped immediately, and appropriate measures need to be taken.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Vitalipid N affects you.

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

Drinking alcohol

Tell your doctor if you drink alcohol.

The effects of alcohol with Vitalipid N use were not studied. Your doctor will decide what you need to do.

Looking after your medicine

Your doctor and hospital pharmacist are responsible for the correct storage, use and disposal of Vitalipid N.

Vitalipid N should be stored below 25°C in a cool dry place, protected from light and away from moisture and heat. Do not freeze. **Do not use this medicine after the expiry date which is stated on the carton label and the ampoule. The expiry date refers to the last day of that month.**

6. Are there any side effects?

All medicines can have side effects. Most of side effects are minor and temporary, however some side effects may need medical attention.

No side effects have been reported with Vitalipid N, however since Vitalipid N must be diluted with other nutrient solutions or likely given together with water soluble vitamins, these may cause unwanted effects in some people. **Tell your doctor or nurse if you notice anything that may be making you feel unwell.**

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Vitalipid N Adult contains

Active ingredient (main ingredient) (10 mL ampoule)	retinol palmitate (Vitamin A palmitate) 1.941 mg *(corresponding to retinol 990 µg)* ergocalciferol (Vitamin D_2) 5 µg dl-alpha-tocopherol (Vitamin E) 9.1 mg phytomenadione (Vitamin K_1) 150 µg

Other ingredients (inactive ingredients)	soya oil egg lecithin glycerol sodium hydroxide (pH adjustment) water for injections
Potential allergens	soya oil egg lecithin

What Vitalipid N Infant contains

Active ingredient (main ingredient) (10 mL ampoule)	retinol palmitate (Vitamin A palmitate) 1.353 mg *(corresponding to retinol 690 µg)* ergocalciferol (Vitamin D_2) 10 µg dl-alpha-tocopherol (Vitamin E) 6.4 mg phytomenadione (Vitamin K_1) 200 µg
Other ingredients (inactive ingredients)	soya oil egg lecithin glycerol sodium hydroxide (pH adjustment) water for injections
Potential allergens	soya oil egg lecithin

Do not take this medicine if you are allergic to any of these ingredients.

Vitalipid N does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Vitalipid N does not contain any preservative.

Vitalipid N comes in a carton of 10 ampoules:

Vitalipid N Adult: Aust R 40252

Vitalipid N Infant: Aust R 40253

What Vitalipid N looks like

Vitalipid N is a milky white 10 mL emulsion in an ampoule.

Who distributes Vitalipid N

Fresenius Kabi Australia Pty Limited

Level 2, 2 Woodland Way

Mount Kuring-gai NSW 2080

Australia

Telephone: 1300 361 004

This leaflet was prepared in March 2023.