Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VITALIPID N. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you or your child given VITALIPID N against any benefits they expect it will have for you or your child.

Please read this leaflet carefully before you are given VITALIPID N. If you have any questions or are unsure about anything, please ask the doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What is VITALIPID N used for

VITALIPID N is a sterile emulsion which provides the body with fat-soluble multivitamins by the intravenous route. When the intake of nutrients or food into the mouth or directly into the gut is not possible, or it is not enough to supply the body's needs, then intravenous nutrients or foods can be given. This is especially important for people whose bodies are under physical stress from illness or recent surgery. During illness or after surgery the body requires nutrition or food.

Before you are given VITALIPID N

You or your child should not be given VITALIPID N if:

- You have an allergy to soya oil, eggs, peanuts or any of the ingredients listed at the end of this leaflet.
- You have very high levels of vitamins in your system.
- You have a sudden, dangerous drop in your blood pressure.
- You have an inability to break down fats.

If you are not sure whether any of these apply to you, check with your doctor.

You should tell your doctor BEFORE given VITALIPID N if the answer to any of the following questions is YES.

- Are you pregnant or trying to become pregnant?
- Are you breastfeeding?
- Are you allergic to soya-, egg- or peanut protein?
- · Do you have liver or kidney disease?
- Are you taking anticoagulants (medicines for preventing blood clotting)?
- Are you 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.

If you have not told your doctors about any of the above, tell them before you are given VITALIPID N.

How to take VITALIPID N

The dose of VITALIPID N will be determined by the doctor or pharmacist. The doctor will supervise your treatment or your child's treatment with VITALIPID N.

VITALIPID N is usually mixed in a bottle or a bag of amino acids, glucose and/or fats, fat-soluble vitamins and given as a continuous infusion into a central vein. An electronic pump may be used to control the speed of the infusion of drip.

Side Effects

Since VITALIPID N has to be diluted with other nutrient solutions, it may cause unwanted effects in some people. All the unwanted effects associated with VITALIPID N may not yet been detected.

If you or your child have/has any unwanted effects during treatment, tell your doctor or pharmacist.

If you are given too much (overdose)

This rarely happens as VITALIPID N is 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.

Otherwise, immediately telephone your doctor or contact the Poisons Information Centre in your country.

Australia: 13 11 26 New Zealand: 0800 764 766.

Storage

Store below 25°C.

Protect from light and do not freeze.

Do not use this medicine after the expiry date which is stated on the carton label and embossed on the ampoule.

The contents of each ampoule of VITALIPID N should be dissolved first and then diluted for single infusion only.

Any unused VITALIPID N should be discarded.

Product Description

What it looks like

VITALIPID N is a sterile, white emulsion in an ampoule. It comes in a carton pack of 10 ampoules.

VITALIPID N can be identified by the following:

Vitalipid N Adult – AUST R 40252

Vitalipid N Infant - AUST R 40253

Inaredients

VITALIPID N ADULT

One mL contains the active ingredients Vitamin A (as retinol palmitate) 99 $\mu g,$ Ergocalciferol 0.5 $\mu g,$ dl-alpha-tocopherol 0.91 mg, Phytomenadione 15 μg and excipients Soya oil 100 mg, Egg lecithin 12 mg, Glycerol 22.0 mg, Sodium hydroxide to pH 8 and Water for Injections to 1 mL.

VITALIPID N INFANT

One mL contains the active ingredients Vitamin A (as retinol palmitate) 69 $\mu g,$ Ergocalciferol 1.0 $\mu g,$ dl-alpha-tocopherol 0.64 mg, Phytomenadione 20 μg and excipients Soya oil 100 mg, Egg lecithin 12 mg, Glycerol 22.0 mg, Sodium hydroxide to pH 8 and Water for Injections to 1 mL.

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

VITALIPID N does not contain any preservative.

Further Information

More detailed information is available from your doctor or pharmacist. Therefore, if you have any concerns about the information or about VITALIPID N ask your doctor or pharmacist.

Sponsor

Australia:

Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way, Mount Kuring-gai NSW 2080 Australia Telephone: (02) 9391 5555

New Zealand:

Fresenius Kabi New Zealand Limited 60 Pavilion Drive Airport Oaks, Auckland 2022 New Zealand

Freecall: 0800 144 892

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Date of Information

This leaflet was prepared in January 2017.