



Package leaflet: Information for the user

**Vitlipid® N Infant**  
Concentrate for emulsion for infusion

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Vitamin A, Vitamin D<sub>2</sub>, Vitamin E and Vitamin K<sub>1</sub>

**Read all of this leaflet carefully before your child is given this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Vitlipid N Infant is and what it is used for
2. What you need to know before your child is given Vitlipid N Infant
3. How your child will be given Vitlipid N Infant
4. Possible side effects
5. How Vitlipid N Infant is stored
6. Contents of the pack and other information

**1. What Vitlipid N Infant is and what it is used for**

Vitlipid N Infant is especially designed for babies and children. It provides fat soluble vitamins in your child's parenteral nutrition when your child cannot eat properly. It is usually used as part of a balanced intravenous diet, together with proteins, fat, carbohydrates, salts and vitamins.

**2. What you need to know before your child receives Vitlipid N Infant**

Your child should not receive Vitlipid N Infant:

- if he/she is allergic (hypersensitive) to Vitamin A, Vitamin D<sub>2</sub>, Vitamin E and Vitamin K<sub>1</sub> or any of the other ingredients of Vitlipid N Infant (listed in Section 6).

**If your child develops a rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), please inform your doctor.**

**Warnings and precautions**  
**Talk to your doctor, or pharmacist before your child is given Vitlipid N Infant:**

- if he/she has ever suffered from an allergic reaction to egg, soya or peanut protein
- if it is undiluted, it will be added to another solution known as Intralipid® before it is given to your child. Your doctor or pharmacist will make sure Vitlipid N Infant it is prepared correctly before it is given to your child.

Your doctor may want to do regular blood tests to check your child's condition.

**Other medicines and Vitlipid N Infant**  
Tell your doctor or nurse if your child is taking or has recently taken or might use any other medicines.

Inform the doctor if your child is taking any medicines to stop his/her blood from clotting (anticoagulants).

**Vitlipid N Infant contains soya bean oil and egg phospholipids.**

Soya bean oil and egg phospholipids may cause allergic reactions. If your child is allergic to soya, peanut or eggs, they must not be given this medicinal product.

**3. How your child will be given Vitlipid N Infant**

Vitlipid N Infant will be given to your child by a doctor or nurse. Your child will receive this medicine by infusion (an injection into a vein). The doctor will decide on the correct dose for him/her to receive.

**Dosage**  
**For preterm and low birth weight babies up to 2.5 kg bodyweight**

The usual daily dose of Vitlipid N Infant is 4 ml for every kg of body weight.

**For all infants and children over 2.5 kg bodyweight and up to 11 years old.**

The daily dose is 10ml/day.

**Children over 11 years old and the elderly.**

The adult preparation Vitlipid N Adult is more suitable for children older than 11 years.

**If your child receives too much Vitlipid N Infant**  
It is very unlikely that your child will receive more infusion than he/she should as doctor or nurse will monitor him/her during the treatment.

However if you think that your child has received too much Vitlipid N Infant, inform the doctor or nurse immediately. Symptoms of overdose include: headache, nausea, vomiting and drowsiness.

If you have any further questions on the use of this medicine, ask the doctor or nurse.

**4. Possible side effects**  
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Vitlipid N Infant contains soya-bean oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut.

If you notice any unwanted effects, please tell the doctor or nurse straight away.

**Reporting of side effects**  
If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

**For UK**  
Yellow Card Scheme  
Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store

**For Ireland**  
HPRA Pharmacovigilance  
Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How Vitlipid N Infant is stored**

**Keep this medicine out of the sight and reach of children.**

Your doctor, pharmacist or nurse is responsible for the correct storage, use and disposal of Vitlipid N Infant.

Store below 25°C. Do not freeze. Keep the container in the outer carton to protect from light. The solution must not be used after the expiry date which is stated on the label.

The expiry date refers to the last day of that month. Any solution remaining after treatment should be disposed of using the approved hospital procedures.

**6. Contents of the pack and other information**

**What Vitlipid N Infant contains**

*Active ingredients*  
Each 1 ml of emulsion contains:  
Retinol (as palmitate) corresponding to retinol (Vitamin A) 69 micrograms (230 IU), Ergocalciferol (Vitamin D<sub>2</sub>) 1 micrograms (40 IU), dl-alpha-tocopherol (Vitamin E) 0.64 mg (0.7 IU), Phytomenadione (Vitamin K<sub>1</sub>) 20 micrograms.

Each 10 ml of emulsion contains:  
Retinol (as palmitate) corresponding to retinol (Vitamin A) 690 micrograms (2,300 IU), Ergocalciferol (Vitamin D<sub>2</sub>) 10 micrograms (400 IU), dl-alpha-tocopherol (Vitamin E) 6.4 mg (7 IU), Phytomenadione (Vitamin K<sub>1</sub>) 200 micrograms.

*Other ingredients*  
Vitlipid N Infant also contains purified soybean oil, purified egg phospholipids, glycerol, sodium hydroxide and water for injections. See section 2 for further information.

**What Vitlipid N Infant looks like and contents of the pack**  
Vitlipid N Infant is a sterile white emulsion (a mixture of oil and water) containing fat soluble vitamins. Each ampoule (small glass container) holds 10 millilitres (10 ml) of emulsion.

**Marketing Authorisation Holder**  
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