



Package leaflet: Information for the user

**Vitlipid® N Adult**  
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 you are 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 side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

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

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

Vitlipid N Adult provides fat soluble vitamins when used together with Intralipid® into your bloodstream when you cannot eat normally. It is usually used as part of a balanced intravenous diet, together with proteins, fat, carbohydrates, salts and other vitamins.

**2. What you need to know before you are given Vitlipid N Adult**

You should not receive Vitlipid N Adult:

- if you are 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 Adult (listed in Section 6).

**If you develop 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 nurse before you are given Vitlipid N Adult. Your doctor or nurse will make sure Vitlipid N Adult is prepared correctly before you receive it.

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

**Other medicines and Vitlipid N Adult**

Tell your doctor or nurse if you are taking or have recently taken or might take any other medicines. Inform your doctor if you are taking any medicines to stop your blood from clotting (anticoagulants) or any Vitamin A supplements.

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before using this medicine. This product contains Vitamin A. High doses of Vitamin A can cause birth defects, especially if taken during the first trimester of pregnancy. You will receive this medicine only if considered essential by your doctor or antenatal clinic.

**Driving and using machines**

Vitlipid N Adult has no effect on driving or using machines.

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

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

**3. How you will be given Vitlipid® N Adult**

Vitlipid N Adult will be given to you by a doctor or nurse. You will receive your medicine by infusion (an injection into a vein). Your doctor will decide on the correct dose for you to receive.

*Dosage*

*Adults and children over 11 years*  
The usual dose of Vitlipid N Adult for adults and children over 11 years of age is 10 millilitres (10 ml) each day. Vitlipid N Adult is not suitable for children under 11 years of age.

**If you receive too much Vitlipid N Adult**

It is very unlikely that you will receive more infusion than you should as your doctor or nurse will monitor you during the treatment. However if you think that you have received too much Vitlipid N Adult, inform your 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 your doctor or nurse.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Vitlipid N Adult 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 your doctor or nurse straight away.

**Reporting of side effects**

If you get 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 Adult 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 Adult.

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 Adult contains**

*Active ingredients*  
Each 1 ml of emulsion contains:  
Retinol (as palmitate) corresponding to retinol (Vitamin A) 99 micrograms (330 IU), Ergocalciferol (Vitamin D<sub>2</sub>) 0.5 micrograms (20 IU), dl-alpha-tocopherol (Vitamin E) 0.91 mg (1 IU), Phytomenadione (Vitamin K<sub>1</sub>) 15 micrograms.

Each 10 ml of emulsion contains:  
Retinol (as palmitate) corresponding to retinol (Vitamin A) 990 micrograms (3,300 IU), Ergocalciferol (Vitamin D<sub>2</sub>) 5 micrograms (200 IU), dl-alpha-tocopherol (Vitamin E) 9.1 mg (10 IU), Phytomenadione (Vitamin K<sub>1</sub>) 150 micrograms.

*Other ingredients*  
Vitlipid® N Adult also contains purified soya-bean oil, purified egg phospholipids, glycerol, sodium hydroxide and water for injections. See section 2 for further information.

**What Vitlipid N Adult looks like and contents of the pack**

Vitlipid N Adult 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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**This leaflet was last revised in December 2021.**