

Vaminolact® solution for infusion

500 ml

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 pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Vaminolact is and what it is used for

Vaminolact is especially designed for new born babies and infants.

It provides nourishment into your child's blood stream when they cannot eat normally. It provides amino acids, which the body will use to make proteins (to build and repair muscles, organs, and other body structures).

Vaminolact is typically mixed with glucose, salts, fats, carbohydrates and vitamins, which together provide complete nutritional needs.

In this leaflet this solution will be referred to as Vaminolact.

2. What you need to know before your child is given Vaminolact

Your child should not use Vaminolact® if:

- a known allergy (hypersensitivity) to Vaminolact or any of the ingredients of Vaminolact mentioned in section 6 (for symptoms of an allergic reaction please refer to section 4).
- seriously reduced liver function
- reduced kidney function (ureamia) and is not on dialysis or another form of blood filtration

treatment Inform your doctor if any of the above conditions apply to your child before treatment with Vaminolact.

Warnings and precautions

Talk to your doctor or pharmacist before using Vaminolact

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed. Exposure of Vaminolact to ambient light, especially after admixtures with trace elements and/or vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure

Before giving this medicine to your child your doctor should know if he/she suffers from:

- cardiac insufficiency - where the heart can't pump enough blood throughout the body or any other heart problems
- a condition where the body has problems using proteins or amino acids
- high potassium levels (hyperkalaemia)
- high sodium levels (hypernatraemia)
- acidosis - higher than normal blood pH levels
- any liver and kidney problems

— Your doctor will carry out regular blood tests to check the condition of your child.

— The doctor or nurse will check that the solution is particle free before it is administered to your child.

— Other medicines and Vaminolact

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

This medicine may cause your child to become deficient in a vitamin known as folic acid, but he /she will usually be given extra vitamins to prevent this.

3. How your child will be given Vaminolact

Your child will receive this medicine by intravenous infusion (IV drip).

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 2).

The dose given to the child will depend on his/her particular condition and will be decided by the doctor.

Dosage

The dose of Vaminolact for new born babies and infants is between 8ml and 35ml for every kg of body weight every 24 hrs. The dose is usually increased gradually during the first week.

The dose for children varies between 14.5ml and 24ml for every kg of body weight every 24 hours. The dose should be given slowly over 24 hours.

If your child receives too much Vaminolact®

It is very unlikely that the child will receive more infusion than it should as a doctor or nurse will monitor your child during the treatment. However, if you think that your child has received too much Vaminolact look for the symptoms described below and inform your doctor or nurse immediately.

The effects of an overdose may include nausea, vomiting, flushing and sweating.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Vaminolact can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are very rare. If your child does get any of the following symptoms after receiving this medicine you should contact your doctor immediately:

- Skin rash
- Swelling (particularly of the lips, face, eyelids, tongue and throat)
- Breathlessness
- Collapse

The following side effects have been observed when infusion was administered too quickly:

- feeling sick
- sweating
- flushing

Other side effects include:

- folate deficiency- shortage of a vitamin known as folic acid
- abnormal liver test results- these will get back to normal after the treatment with Vaminolact is finished
- cholestasis- a condition in which bile is not flowing properly from the liver to the intestines
- soreness and tenderness of the vein
- thrombosis (the formation of a clot) in the vein where the injection is given

The symptoms of thrombosis include:

- Pain, swelling and redness at the blood clot site
- An itchy rash at the clot site
- Warm skin around the clot
- A mild fever
- Major veins that stand out from your skin

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. In the UK you can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

In Ireland you can report side effects directly to HPRA Pharmacovigilance, Earlsfort Terrace, IRL- Dublin 2.

Or by email to medsafety@hpri.ie

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

5. How to store Vaminolact

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Do not freeze.

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

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not use if bottle is leaking or if solution is cloudy or contains a precipitate. For single use only and discard any unused contents.

Do not throw away medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 2).

6. Contents of the pack and other information

What Vaminolact solution for infusion contains

Each 1000 ml of Vaminolact contains the following active ingredients:

Amino Acids	Amount
Alanine	6.3 grams
Arginine	4.1 grams
Aspartic acid	4.1 grams
Cysteine/Cystine	1.0 grams
Glutamic acid	7.1 grams
Glycine	2.1 grams
Histidine	2.1 grams
Isoleucine	3.1 grams
Leucine	7.0 grams
Lysine	5.6 grams
Methionine	1.3 grams
Phenylalanine	2.7 grams
Proline	5.6 grams
Serine	3.8 grams
Taurine	0.3 grams
Threonine	3.6 grams
Tryptophan	1.4 grams
Tyrosine	0.5 grams
Valine	3.6 grams

Vaminolact also contains water for injections.

What Vaminolact® looks like and contents of pack

Vaminolact is a clear, colourless to slightly yellow solution of amino acids and salts. It is available in glass bottles with a rubber closure that contain 100 ml or 500 ml of solution.

Not all pack sizes may be marketed.

Marketing authorisation holder

For UK :

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For IRL:

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