Package leaflet: Information for the user

Vaminolact solution for infusion

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 possible 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

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 (inbags and administration sets) should be protected from light exposure until administration is completed. Exposure ofVaminolact to ambient light, especially after admixtures with trace elements and/or vitamins, generates peroxides and otherdegradation 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 dosage should be given in accordance with the below table based on weight range and age:

Age groups (age range)	**Dosage range**	
	mL/kg bw/d	**g AA/kg bw/d**
Neonates (birth to <1 month of age)		
Preterm Neonates		
1st Day	23 to 38 mL/kg/d	1.5 to 2.5 g AA/kg/d
≥2nd Day	38 to 54 mL/kg/d	2.5 to 3.5 g AA/kg/d
Gradual dose increase during the first days of infusion should be used, starting with a dose such as 23 to 38 mL/kg/d (corresponding to 1.5 to 2.5 g amino acids/kg/d) on the first day and increasing to 38 to 54 (corresponding to 2.5 to 3.5 g amino acids/kg/d) on the second day onwards.		
Term Neonates	23 to 46 mL/kg/d	1.5 to 3.0 g AA/kg/d
Gradual dose increase to the target dose should be used during the first days of infusion.		
Infants (≥1 month to <2 years of age)	15 to 38 mL/kg/d	1.0 to 2.5 g AA/kg/d
Children (≥2 years to <12 years of age)	15 to 31 mL/kg/d	1.0 to 2.0 g AA/kg/d
Adolescents (≥12 years to <17 years of age)	15 to 31 mL/kg/d	1.0 to 2.0 g AA/kg/d

AA = amino acids; bw = body weight

The duration of infusion should be at least 8 hours, preferably 12 hours as cyclic infusion or 24 hours as continuous infusion. In neonates and infants, the recommended duration of continuous infusion is 24 hours/d.

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.

For the UK:
You can report side effects directly to the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

For IE:
You can report side effects directly to HPRA Pharmacovigilance website: www.hpra.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, 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	Methionine	1.3 grams
Arginine	4.1 grams	Phenylalanine	2.7 grams
Aspartic acid	4.1 grams	Proline	5.6 grams
Cysteine/Cystine	1.0 grams	Serine	3.8 grams
Glutamic acid	7.1 grams	Taurine	0.3 grams
Glycine	2.1 grams	Threonine	3.6 grams
Histidine	2.1 grams	Tryptophan	1.4 grams
Isoleucine	3.1 grams	Tyrosine	0.5 grams
Leucine	7.0 grams	Valine	3.6 grams
Lysine	5.6 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 package sizes may be marketed.

Marketing Authorisation Holder

For UK:
Fresenius Kabi Limited
Cestrian Court, Eastgate Way
Manor Park
Runcorn, Cheshire
WA7 1NT, UK

For IE:
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1, 61352 Bad Homburg, v.d.Höhe, Germany

Manufacturer:

Fresenius Kabi Austria GmbH
Hafnerstraße 36 8055 Graz
Austria

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The following information is intended for healthcare professionals only.

Method of administration:
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

Special warnings and precautions for use*:*

Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products. When used in neonates and children below 2 years, Vaminolact should be protected from ambient light until administration is completed.