Product Name:		Territory:
Aminosteril Infant 6%		**ID**
Type of Packaging:	Dosage:	
Leaflet	**100 ml**	
Material number:	2-D-Matrix Code:	
M0xxxxx/01 ID	**M0xxxxx/01 ID**	
Pharma-Code (Laetus):	EAN-Code:	
x	**x**	
Dimension:	Font:	Size:
180 x 294 mm 1 Page	**Arial**	**8**

Colours:	1. Draft	02.09.2021, 09:30
• Schwarz	1. Corr	09.09.2021, 11:00
• Fold lines	2. Corr	01.04.2022, 11:15
	3. Corr	

Mock up

Operator:
Roberto Grill

AMINOSTERIL INFANT 6 %
ASAM AMINO, TAURINE
INFUS

COMPOSITION

Tiap 1 liter mengandung:

L-Leucine	7,80	g
L-Isoleucine	4,80	g
L-Lysine acetate	7,20	g
L-Methionine	1,872	g
L-Phenylalanine	2,25	g
L-Threonine	2,64	g
L-Tryptophan	1,206	g
L-Valine	5,40	g
L-Arginine	4,50	g
L-Histidine	2,856	g
Glycine	2,49	g
L-Taurine	0,241	g
L-Serine	4,602	g
L-Alanine	5,58	g
L-Proline	5,826	g
N-Acetyl-L-tirosine	3,106	g
N-Acetyl-cysteine	0,42	g
L-malic acid	1,572	g
Total amino acids	60	g/l
Total nitrogen content	9	g/l

DRUG ACTION

Parenteral Infusion of amino acids is necessary, when oral or enteral supply with protein is impossible. Especially newborn infants, babies and children require constant provision of protein for proper organ function, development and growth.
Intravenously given amino acids are proven to be metabolised like those derived from nutrient proteins. The composition of aminosteril infant 6% has been specifically formulated to provide an optimal nitrogen source of nutritional support and therapy for pediatric patients. The solution is designed to meet the requirements for protein – building substances of pediatric patients in different disease conditions.
The amino acid pattern can be assessed suitable for the maintenance of the nutritional status.

INDICATION

Parenteral nutrition for prophylaxis and treatment of protein deficiency in paediatrics when oral food intake is either contraindicated or impossible as in cases like :
Premature birth.
Small – for date syndromes.
Gastro – intestinal diseases and malformations.
Peri operatively in paediatric surgery
Intensive care of infants following burns and severe injuries.

DOSAGE / POSOLOGY

For intravenous infusion
Max. Infusion dosage:
Up to 0.1 g amino acids/ kg b.w. and h = 1.67 ml / kg b.w & h.
Max. daily dosage:
When administered during the first days of life, dosage should be restricted to 1 g amino acids per kg body weight per day.

1st year of living : 1.5 – 2.5 g amino acids / kg b.w.
2nd year of living : 1.5 g amino acids / kg b.w.
3rd to 5th year of living : 1.5 g amino acids / kg b.w.
6th to 10th year of living : 1.0 g amino acids / kg b.w.
11th to 14th year of living : 1.0 g amino acids / kg b.w.

The solution is administered as long as Parenteral nutrition is required.

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 Special Warnings / Precautions).

SPECIAL WARNINGS / PRECAUTIONS

Do not use Aminosteril Infant 6% after expiry date.
Use only clear solutions and undamaged containers.
Keep drugs out of the reach of children.

Administration of amino – acid solution may cause folate deficiency and supplementary folic acid should be administered.
In order to ensure optimum metabolic utilisation of the amino acids administered, therapy should be adequately supported by an energy supply of 35 kcal (145 KJ) per gram of amino acids.
Over dosage or a too rapid infusion may manifest in the form of nausea, shivering, vomiting and increased renal amino acid losses.

In such cases, the infusion should be interrupted and eventually continued at a reduced infusion rate.

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, Aminosteril infant 6% should be protected from ambient light until administration is completed (see sections Dosage / Posology).

REMARK

Too rapid infusion may result inrenal losses causing amino acid imbalances.
Electrolytes should be administered according to the requirements.

SIDE EFFECT

Local reactions consisting of erythema, phlebitis and thrombosis at the infusion site can occur with peripheral infusion. Generalized flushing, vomiting and fever furing infusion of amino acid solutions have been reported.

CONTRAINDICATION

Aminosteril Infant 6% is contraindicated in patients with inborn errors of amino acids metabolism, hepatic coma and untreated anuria (renal insufficiency), manifest cardiac insufficiency, hyperhydration and hypokalemia.

Patients with insufficient renal or hepatic function require and individual dosage.

DRUG INTERACTION

Because of the increased risk of microbiological contaminations and imcompatibilities, amino acid solution should not be mixed with other drugs.

REMARK

The addition of drugs may alter the chemical and physical properties of the solution and may therefore give rise to toxic reactions. Should it nevertheless become necessary to add drugs Aminosteril Infant 6%, it is imperantive to ensure sterility, complete mixing and comtibility. The same applies for the adding of lipid emulsions, trace elements and vitamins for complete parenteral nutrition mixtures.

PRESENTATION

Bottle 100ml Reg No : DKI1381203349A1

STORE PROTECTED FROM LIGHT AND NOT ABOVE 30°C

HARUS DENGAN RESEP DOKTER

Manufactured by
Fresenius Kabi Austria, GmbH
Hafnerstrabe 36, A-8055 Graz

For
Fresenius Kabi Deustchland GmBH
61346 Bad Homburg v.d.H
Germany

Imported by
Fresenius Kabi Combiphar
Bandung Barat - Indonesia

FRESENIUS KABI

M0xxxxx/01 ID

DISETUJUI OLEH BPOM : 07/06/2023

ID : EREG10024312300006