Product Name:		Territory:
Aminosteril Infant 10%		**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
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• Fold lines	2. Corr	
	3. Corr	

Mock up

Operator: **Roberto Grill**

AMINOSTERIL INFANT 10 %
ASAM AMINO, TAURINE
INFUS

1000 ml contains:

L-leucine	13.00	g
L-isoleucine	8.00	g
L-lysine acetate	12.00	g
= L-lysine 8.51 g		
L-methionine	3.12	g
L-phenylalanine	3.75	g
L-threonine	4.40	g
L-tryptophan	2.01	g
L-valine	9.00	g
Arginine	7.50	g
L-histidine	4.76	g
Glycine	4.15	g
L-taurine	0.40	g
L-serine	7.67	g
L-alanine	9.30	g
L-proline	9.71	g
N-acetyl-L-tyrosine	5.176	g
= L-tyrosine 4.20 g		
N-acetyl-L-cysteine	0.70	g
= L-cysteine 0.52 g		
L-malic acid	2.62	g

Total amino acids:	100	g/l
Total nitrogen content:	14.9	g/l
Titration acidity:	25 - 45 mmol	NaOH/l
pH-value:	5.5 - 6.0	
Theoretical osmolarity:	885	mosm/l

Other constituents: Water for injections

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, developments and growth.

Intravenously given amino acids are proven to be metabolized like those derived from nutrient proteins. The composition of aminosteril infant 10% has been specifically formulated to provide an optimal nitrogen source for nutritional support and therapy for pediatric patient. The solution is design to meet the requirements for protein – building substances of pedriatic patients in different disease conditions. The amino acid pattern can be assessed suitable for the maintenance of the nutritional status.

INDICATIONS

Parenteral nutrition for prophylaxis and treatment of protein deficiency in pediatrics 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 pediatric surgery.
Intensive care of infants following burns and severe injuries.

DOSAGE / POSOLOGY

For intravenous infusion
Max. infusion dosage:
Up to 0.1 amino acids / kg b.w. and h = 1.0 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 WARNING / PRECAUTIONS

Do not use Aminosteril Infant 10% after expiry date.
Use only clear solution 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 utilization 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 acids 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 10% should be protected from ambient light until administration is completed (see sections Dosage / Posology).

REMARK

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

SIDE EFFECT

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

CONTRA INDICATION

Aminosteril Infant 10% is contraindicated in patients with inborn errors of amino acids metabolism, hepatic coma and untreated anuaria (renal insufficiency), manifest cardiac insufficiency, hyperhydration and hypokalemia.
Patient with insufficients renal or hepatic function require and individual dosage.

DRUG INTERACTION

Because of the increased risk of microbiological contaminations and imcompatibillities, amino acids solutions should not be mixed with other drugs

REMARK

The addition of drug may after the chemical and physical properties of the solution and may therefore give rise to toxic reactions.
Should it nevertheless become necessary to add drugs to Aminosteril Infant 10%, it is imperantive to ensure sterility, complete mixing and comtibility. The same applies for the adding of lipid emulsions, trace elements and vitamin for complete parenteral nutrition mixtures.

PRESENTATION
Bottle 100 ml Reg No: DKI1681203349B1

Store below 30°C, protect from light.
Shelf life: 2 years

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
PT. Fresenius Kabi Combiphar
Bandung - Indonesia

FRESENIUS KABI

M0xxxxx/01 ID

DISETUJUI OLEH BPOM : 07/04/2022

ID : EREG100243VR12100035