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B. Braun Melsungen AG · 34209 Melsungen, Germany

Composition	
1000 ml solution for infusion contains:	
- active substances:	
Amino acids:	
Isoleucine	
Leucine	
Lysine hydrochloride	
(equivalent to lysine 6.85 g)	
Methionine	
Phenylalanine	
Threonine	
Tryptophan	
Valine	
Arginine Histidine	
Alanine	
Glycine	
Aspartic acid	
Glutamic acid	
Proline	
Serine	
Tyrosine	
Electrolytes:	
Sodium acetate trihydrate	
Sodium hydroxide	
Potassium acetate	
Magnesium chloride hexahydrate	
Disodium hydrogen phosphate dodecahydrate	
- excipients:	
Acetylcysteine	
Citric acid monohydrate	
Water for injection	
Nitrogen (protective gas)	
Amino acid content	
Total nitrogen content	
Caloric value:	1675 kJ/l ≙ 4
Theoretical osmolarity:	1021
Titration acidity (pH 7.4):	approx. 2
pH:	
Electrolyte concentrations:	
Sodium	
Potassium	
Magnesium	
Acetate	
Chloride	
Phosphate Citrate	
Pharmaceutical form and contents	00 ml 1000 l
Solution for infusion in glass bottles of 250 ml, 50	JU MI, 1000 MI
Available pack sizes 10 x 250 ml	
10 x 500 ml	
6 x 1000 ml	

**Pharmaco-therapeutic category** Solutions for parenteral nutrition, combinations | -

## Aminoplasmal B. Braun 10% E

Solution for Infusion

	Marketing authorisation holder and manufacturer	
	B. Braun Melsungen AG	
	Carl-Braun-Str. 1	
	34212 Melsungen, Germany	
5.00 g	Postal address	
8.90 g	34209 Melsungen, Germany	
8.56 g	Indications	
	Supply of amino acids as a substrate for protein synthesis in parenteral nutri-	
4.40 g	tion, when oral or enteral nutrition is impossible, insufficient or contra-indi-	
4.70 g	cated.	
4.20 g 1.60 g	In parenteral nutrition, amino acid infusions should always be combined with an adequate calorie supply, e.g. in the form of carbohydrate infusions.	
6.20 g		
11.50 g	Contraindications	
3.00 g	<ul> <li>Hypersensitivity to an amino acid present in the solution</li> <li>Congenital abnormalities of amino acid metabolism</li> </ul>	
10.50 g	- Severe circulation disorders with vital risk (e.g. shock)	
12.00 g	- Hypoxia	
5.60 g	- Metabolic acidosis	
7.20 g	- Advanced liver disease	
5.50 g	- Severe renal insufficiency without treatment by haemodialysis or haemofil-	
2.30 g	tration	
0.40 g	<ul> <li>High and pathological plasma concentration of any of the electrolytes includ-</li> </ul>	
	ed in the product	
2.858 g	- Use in children under 2 years of age	
0.360 g	- General contraindications for infusion therapy:	
2.453 g 0.508 q	<ul> <li>uncompensated cardiac insufficiency</li> <li>acute pulmonary oedema</li> </ul>	
3.581 g	- hyperhydration	
5.501 g		
	Pregnancy and lactation Studies in pregnant or breastfeeding women have not been conducted with this	
	medicinal product. There are no pre-clinical data regarding the administration	
	of Aminoplasmal B. Braun 10% E during pregnancy.	
	Aminoplasmal B. Braun 10% E should therefore be administered with caution	
100 g/l	during pregnancy and lactation only if clearly indicated and after carrying out	
15.8 g/l	a benefit/risk analysis.	
J/I ≙ 400 kcal/I	Special warnings and precautions for use	
1021 m0sm/l	Aminoplasmal B. Braun 10% E should only be administered after careful bene-	
orox. 26 mmol/l	fit/risk assessment in the presence of disorders of acid metabolism of other ori-	
5.7-6.3	gin than stated under "Contraindications".	
mmol/l	In patients with liver or renal insufficiency, the dose must be adjusted accord-	
50	ing to individual requirements. Caution should be exercised in patients with increased serum osmolarity.	
25	Hypotonic dehydration should be corrected by adequate supply of fluid and	
2.5	electrolytes prior to parenteral nutrition.	
46 52	Serum electrolytes, blood glucose, fluid balance, acid-base balance and renal	
52 10	function (BUN, creatinine) should be monitored regularly.	
2.0	Monitoring should also include serum protein and liver function tests.	
210	Care should be exercised in the administration of large volume infusion fluids	
nl	to patients with cardiac insufficiency.	
	Aminoplasmal B. Braun 10% E can be used as part of a total parenteral nutri-	
	tion regimen in combination with adequate amounts of energy supplements	
	(carbohydrate solutions, fat emulsions), vitamins, trace elements and elec-	
	trolytes.	
	The catheter insertion site should be checked daily for signs of inflammation or	

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ed in the section "Dosage". <b>Dosage, method and duration o</b> Intravenous use (central venous The dosage is adjusted according trolytes, and fluids depending of tional status and degree of catal <i>Adults:</i> Daily dose: 10 - 20 ml/kg body weight (BW) Maximum daily dose: 20 ml/kg BW Maximum infusion or drop rate: 1 ml/kg per BW and per hour <i>Children:</i> The dosages for children represe individually adjusted according ease. Daily dose for 3-5 years of age: 15 ml/kg BW Daily dose for 6-14 years of age: 10 ml/kg BW Maximum infusion rate: 1 ml/kg per BW and per hour Aminoplasmal B. Braun 10% E n indication for parenteral nutritio Aminoplasmal B. Braun 10% E n indication for parenteral nutritio Aminoplasmal B. Braun 10% E is In parenteral nutrition, amino a calorie sources, essential fatty ac A sterile infusion set must be usi If it is necessary to add other nu and trace elements to this produ admixing must be performed u should be thoroughly mixed and From the microbiological point of Parenteral nutrition of the microbiological point of Parenteral nutrition of parenteral nutrition Anter of the microbiological point of Parenteral nutrition of the microbiological point of Parenteral nutrition of parenteral nutrition of Parenteral	<ul> <li>infusion).</li> <li>to the individual need for amino acids, electro the clinical condition of the patient (nutribulism due to underlying disease).</li> <li>▲ 1.0-2.0 g amino acids/kg BW</li> <li>▲ 700-1400 ml for 70 kg BW</li> <li>▲ 2.0 g amino acids/kg BW</li> <li>▲ 140 g amino acids for 70 kg BW</li> <li>▲ 1400 ml for 70 kg BW</li> <li>▲ 0.1 g amino acids/kg per BW and per hour</li> <li>▲ 25 drops/min for 70 kg BW</li> <li>▲ 1.17 ml/min for 70 kg BW</li> <li>▲ 1.5 g amino acids/kg BW</li> <li>▲ 1.0 g amino acids/kg BW</li> <li>▲ 1.0 g amino acids/kg BW</li> <li>▲ 0.1 g amino acids/kg BW</li> <li>▲ 1.5 g amino acids/kg BW</li> <li>▲ 1.0 g amino acids/kg Per BW and per hour the apply of a particular distribution.</li> <li>a only one component of parenteral nutrition.</li> <li>a electrolytes, vitamins, and trace elements.</li> </ul>	ifest as nausea In such cases t rate if necessa Undesirable ef Like all medicin The following t very common common uncommon rare very rare Adverse effects enteral nutritic Uncommon: Gastrointestina General disorde Note If you notice an pharmacist. Special precau Keep out of the Do not use after Keep the bottle Do not store al Do not freeze. Storage below gentle heating ture when hea Only use if the aged. A sterile infusio	<ul> <li>Aminoplasmal B. Braun 10% can cause side effects.</li> <li>terms are used to describe the frequency of adverse effects:</li> <li>occurrence in 1 or more in 10 treated patients</li> <li>occurrence in 1 to 10 in 1000 treated patients</li> <li>occurrence in 1 to 10 in 10,000 treated patients</li> <li>occurrence in 1 to 10 in 10,000 treated patients</li> <li>occurrence in 1 to 10 in 10,000 treated patients</li> <li>occurrence in less than 1 in 10,000 treated patients, including isolated cases</li> <li>as are not specific for this product but can arise as a result of paron, particularly at the beginning.</li> <li>al disorders: nausea, vomiting</li> <li>ers: headache, shivering, fever</li> <li>ny side effects not listed in this leaflet, please tell your doctor or</li> <li><b>Attions for storage</b></li> <li>e reach and sight of children.</li> <li>er the expiry date stated on the label and on the outer carton.</li> <li>es in the outer carton in order to protect from light.</li> <li>bove 25°C.</li> <li>15°C can lead to the formation of crystals which dissolve upon to 25°C. Gently agitate the container to homogenise the mixting.</li> <li>esolution is clear and the container and the closure are undamon set must be used.</li> <li>only. After infusion any residual product must be disposed of.</li> </ul>
should be thoroughly mixed and From the microbiological point of			



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