

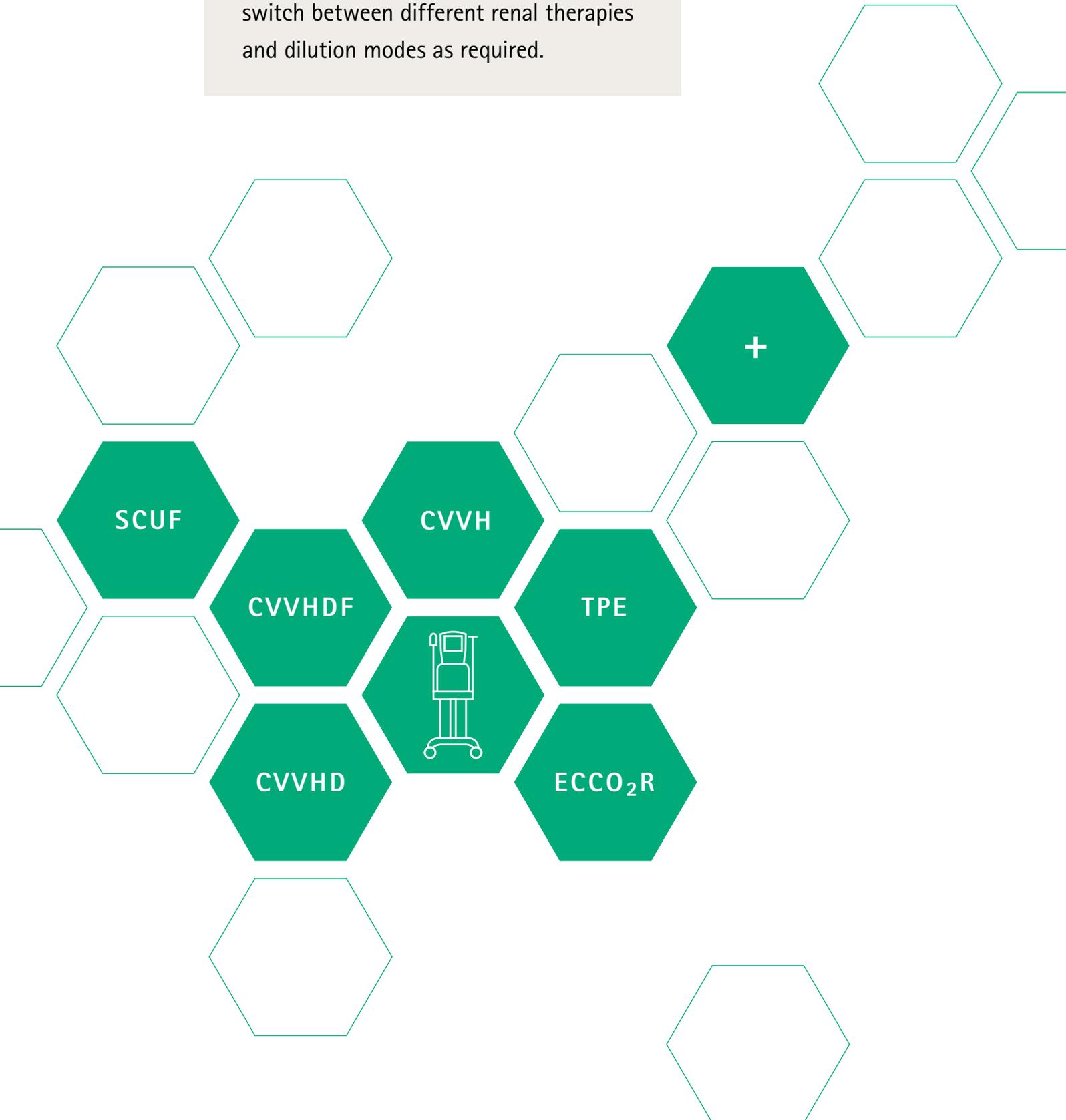
# OMNI<sup>®</sup>

One life means  
everything



# Therapeutic Flexibility

Why settle for less? With OMNI® you can switch between different renal therapies and dilution modes as required.

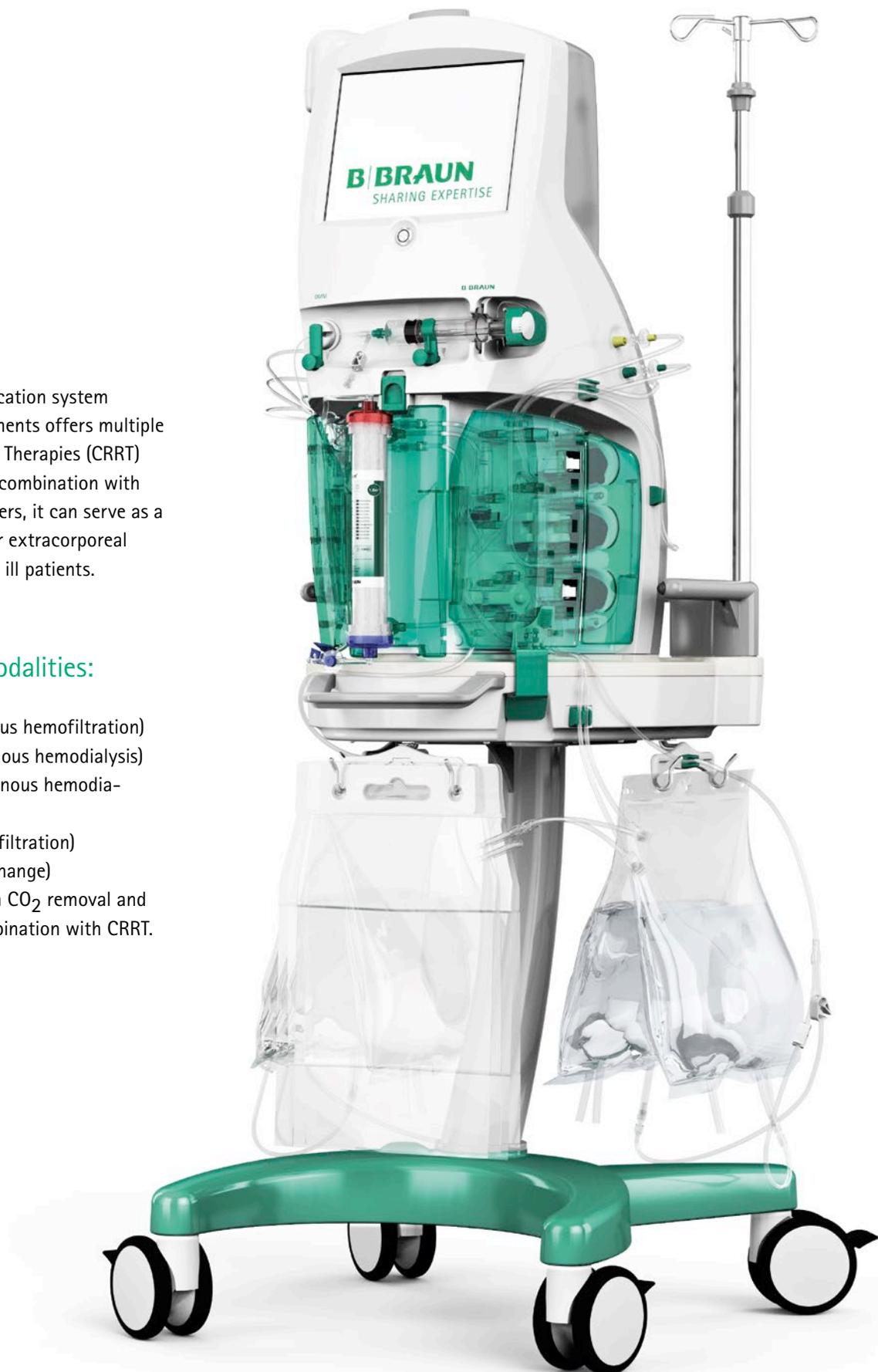




The OMNI®\* acute blood purification system for extracorporeal blood treatments offers multiple Continuous Renal Replacement Therapies (CRRT) and anticoagulation modes. In combination with secondary cartridges or adsorbers, it can serve as a platform for other therapies for extracorporeal multiorgan support of critically ill patients.

### Available treatment modalities:

- CVVH (continuous venovenous hemofiltration)
- CVVHD (continuous venovenous hemodialysis)
- CVVHDF (continuous venovenous hemodiafiltration)
- SCUF (slow continuous ultrafiltration)
- TPE (therapeutic plasma exchange)
- The system can also perform CO<sub>2</sub> removal and adsorbative therapies in combination with CRRT.



# Treatment Effectiveness

The OMNI® can give you the freedom and the capability to offer your patients the appropriate form of therapy.

As one of the worldwide leaders in the field of extracorporeal blood treatments, B. Braun always strives for a higher level of quality and reliability:



98% renal dose achievement with less than 5% down time in CVVHD RCA<sup>1</sup> by compensating certain therapy interruptions



Smart bag movement recognition to reduce unnecessary alarms and therapy interruptions



Patient Care Mode for temporary treatment pauses



An intelligent fluid concept for reduction of alarms and regulation of fluid volumes





# Handling & Design

OMNI® has been designed with its users in mind. Thanks to the compact design and low weight, it is easy to move the machine inside the ICU. The fully pre-connected Plug & Play OMNIset® can reduce workloads for setup, loading and priming and shorten time required for training.



Automatic priming time of approximately 10 minutes for CRRT and 11 minutes for TPE



Intuitive user interface with step-by-step guidance through the therapy process





Lightweight device (approximately 62 kg) with good mobility and a small footprint allows for easy transport and positioning in the ICU



Barcode scanner ensures the right OMNIset® for the right therapy



Customizable screensaver visible from a distance of 10 meters



Adjustable screen brightness and alarm volumes to align with Silent ICU standards

# OMNIset®

Fully pre-connected Plug & Play set

OMNIset®\* is a pre-connected Plug & Play set designed to provide full flexibility for healthcare professionals to reduce preparation time and workload during the set-up, loading and priming process.





## Therapeutic Flexibility

- The fully pre-connected OMNIset® and the easy step-by-step on-screen instructions make setting up the OMNI® simple and fast
- Auto-priming of only 10 minutes for CRRT modalities

## Handling & Design

- Fully pre-connected tubing set (including Integrated Warmer bag), color coded lines and connectors, with additional written indication on the Citrate & Calcium lines help to prevent mistakes during set-up

## OMNIset®\*

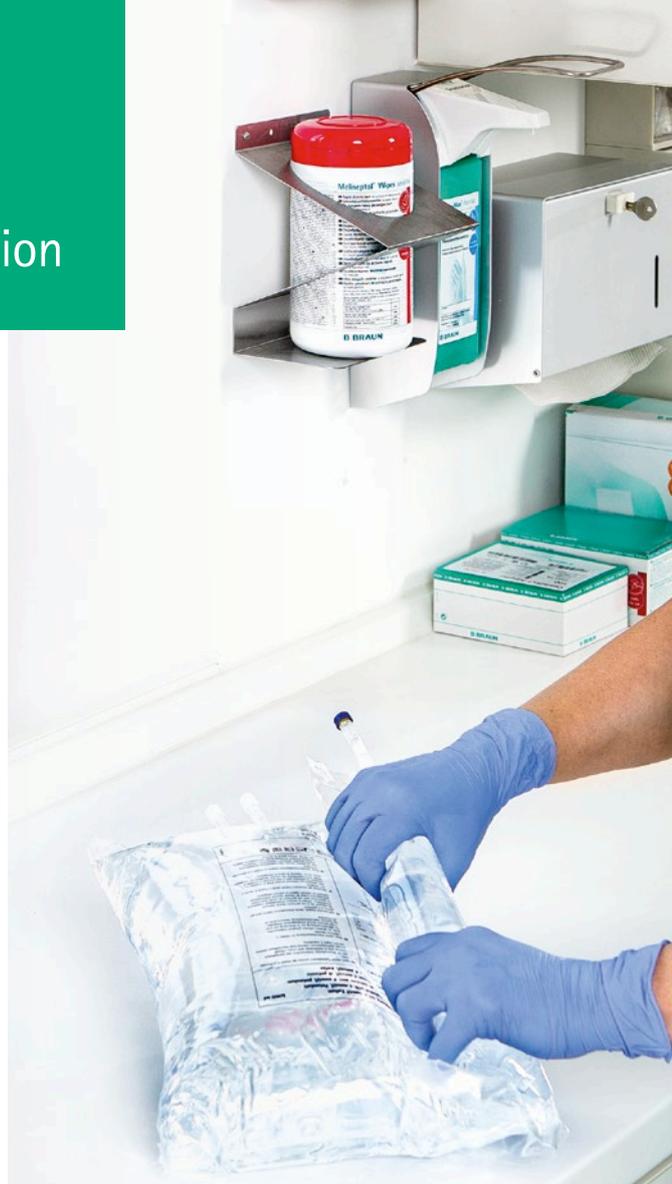
Product	Range
OMNIset®	0.8 m <sup>2</sup> – 1.6 m <sup>2</sup>
OMNIset® Pro	0.8 m <sup>2</sup> – 1.6 m <sup>2</sup>
OMNIset® TPE	0.5 m <sup>2</sup> – 0.7 m <sup>2</sup>
OMNIset® L validated for up to 96h	1.6 m <sup>2</sup>
OMNIset® Plus	1.6 m <sup>2</sup>
OMNIset® ECCO2R	1.6 m <sup>2</sup>

## OMNIbag®

Product	Size
OMNIbag®	7000 ml Effluent Bag standard
OMNIbag®	7000 ml Effluent Bag with drainage function

# Two solutions - one goal

Driving progress in acute blood purification



## Duosol® solution for hemofiltration

A sterile ready-to-use solution for hemofiltration indicated for use in patients with acute renal failure of any cause requiring continuous hemofiltration.

### Composition of the ready-to-use solution

Na+ mmol/l	K+ mmol/l	Ca <sup>++</sup> mmol/l	Mg <sup>++</sup> mmol/l	Cl <sup>-</sup> mmol/l	HCO <sub>3</sub> <sup>-</sup> mmol/l	Glucose mmol/l	Theoret. osmolarity mOsm/l
140	0	1.5	0.5	109	35.0	5.6	292
140	2	1.5	0.5	111	35.0	5.6	296
140	4	1.5	0.5	113	35.0	5.6	300

Packaging type: 1 box contains 2 bags, pallet assembly: 60 boxes

## B. Braun Bicarbonate calcium-free solution

A dialysis solution for CVVHD when using citrate anticoagulation.

### Composition of the ready-to-use solution

Na+ mmol/l	K+ mmol/l	Ca <sup>++</sup> mmol/l	Mg <sup>++</sup> mmol/l	Cl <sup>-</sup> mmol/l	HCO <sub>3</sub> <sup>-</sup> mmol/l
136	4	0	0.75	116.5	25
136	2	0	0.75	114.5	25

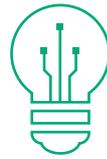
Packaging type: 1 box contains 2 bags, pallet assembly: 60 boxes

Other formulations and solutions suitable for the use under regional citrate anticoagulation are available upon request.

Please contact your B. Braun representative.



## The Duosol<sup>®</sup> solution and bag



### Implementing innovation

Our aim in research and development was not only to provide a perfect solution but also a convenient and contemporary double-chamber bag system.

With Duosol<sup>®</sup> you have a versatile ready-to-use solution in a handy double-chamber bag made of materials fully tested for biocompatibility.



### Features at a glance:

- Double-chamber bag
- PVC, Latex and DEHP-free
- Bicarbonate buffered
- Suitable for CRRT
- Simple mixing and usage
- 2-year shelf life

# Mandatory Information

## Duosol® without Potassium/with 2 mmol/l Potassium/with 4 mmol/l Potassium Hemofiltration Solution

### Composition:

#### Duosol® without Potassium Hemofiltration Solution:

Active ingredients:	Small chamber Electrolyte solution		Large chamber Bicarbonate solution	
	555 ml contain	per 1000 ml	4445 ml contain	per 1000 ml
Sodium chloride	2.34 g	4.21 g	27.47 g	6.18 g
Calcium chloride dihydrate	1.10 g	1.98 g	–	–
Magnesium chloride hexahydrate	0.51 g	0.91 g	–	–
Glucose monohydrate	5.49 g	9.90 g	–	–
corresponding to anhydrous glucose	5.0 g	9.0 g	–	–
Sodium hydrogen carbonate	–	–	15.96 g	3.59 g
<b>Electrolytes:</b>	<b>[mmol/chamber]</b>	<b>[mmol/l]</b>	<b>[mmol/chamber]</b>	<b>[mmol/l]</b>
Na <sup>+</sup>	40.0	72	660	149
Ca <sup>2+</sup>	7.5	13.5	–	–
Mg <sup>2+</sup>	2.5	4.5	–	–
Cl <sup>-</sup>	75.0	135	470	106
HCO <sub>3</sub> <sup>-</sup>	–	–	190	42.8
Theoretical osmolarity [mOsm/l]	275		297	

Composition of the ready-to-use hemofiltration solution after mixing: 1000 ml of ready-to-use hemofiltration solution contain: Na<sup>+</sup> 140 mmol/l; Ca<sup>2+</sup> 1.5 mmol/l; Mg<sup>2+</sup> 0.5 mmol/l; Cl<sup>-</sup> 109 mmol/l; HCO<sub>3</sub><sup>-</sup> 35.0 mmol/l; anhydrous glucose 5.6 mmol/l (equivalent to 1.0 g).

#### Duosol® with 2 mmol/l Potassium Hemofiltration Solution:

Active ingredients:	Small chamber Electrolyte solution		Large chamber Bicarbonate solution	
	555 ml contain	per 1000 ml	4445 ml contain	per 1000 ml
Sodium chloride	2.34 g	4.21 g	27.47 g	6.18 g
Potassium chloride	0.74 g	1.34 g	–	–
Calcium chloride dihydrate	1.10 g	1.98 g	–	–
Magnesium chloride hexahydrate	0.51 g	0.91 g	–	–
Glucose monohydrate	5.49 g	9.90 g	–	–
corresponding to anhydrous glucose	5.0 g	9.0 g	–	–
Sodium hydrogen carbonate	–	–	15.96 g	3.59 g
<b>Electrolytes:</b>	<b>[mmol/chamber]</b>	<b>[mmol/l]</b>	<b>[mmol/chamber]</b>	<b>[mmol/l]</b>
Na <sup>+</sup>	40.0	72	660	149
K <sup>+</sup>	10.0	18.0	–	–
Ca <sup>2+</sup>	7.5	13.5	–	–
Mg <sup>2+</sup>	2.5	4.5	–	–
Cl <sup>-</sup>	85.0	153	470	106
HCO <sub>3</sub> <sup>-</sup>	–	–	190	42.8
Theoretical osmolarity [mOsm/l]	311		297	

Composition of the ready-to-use hemofiltration solution after mixing: 1000 ml of ready-to-use hemofiltration solution contain: Na<sup>+</sup> 140 mmol/l; K<sup>+</sup> 2.0 mmol/l; Ca<sup>2+</sup> 1.5 mmol/l; Mg<sup>2+</sup> 0.5 mmol/l; Cl<sup>-</sup> 111 mmol/l; HCO<sub>3</sub><sup>-</sup> 35.0 mmol/l; anhydrous glucose 5.6 mmol/l (equivalent to 1.0 g).

#### Duosol® with 4 mmol/l Potassium Hemofiltration Solution:

Active ingredients:	Small chamber Electrolyte solution		Large chamber Bicarbonate solution	
	555 ml contain	per 1000 ml	4445 ml contain	per 1000 ml
Sodium chloride	2.34 g	4.21 g	27.47 g	6.18 g
Potassium chloride	1.49 g	2.68 g	–	–
Calcium chloride dihydrate	1.10 g	1.98 g	–	–
Magnesium chloride hexahydrate	0.51 g	0.91 g	–	–
Glucose monohydrate	5.49 g	9.90 g	–	–
corresponding to anhydrous glucose	5.0 g	9.0 g	–	–
Sodium hydrogen carbonate	–	–	15.96 g	3.59 g
<b>Electrolytes:</b>	<b>[mmol/chamber]</b>	<b>[mmol/l]</b>	<b>[mmol/chamber]</b>	<b>[mmol/l]</b>
Na <sup>+</sup>	40.0	72	660	149
K <sup>+</sup>	20.0	36.0	–	–
Ca <sup>2+</sup>	7.5	13.5	–	–
Mg <sup>2+</sup>	2.5	4.5	–	–
Cl <sup>-</sup>	95.0	171	470	106
HCO <sub>3</sub> <sup>-</sup>	–	–	190	42.8
Theoretical osmolarity [mOsm/l]	347		297	

Composition of the ready-to-use hemofiltration solution after mixing: 1000 ml of ready-to-use hemofiltration solution contain: Na<sup>+</sup> 140 mmol/l; K<sup>+</sup> 4.0 mmol/l; Ca<sup>2+</sup> 1.5 mmol/l; Mg<sup>2+</sup> 0.5 mmol/l; Cl<sup>-</sup> 113 mmol/l; HCO<sub>3</sub><sup>-</sup> 35.0 mmol/l; anhydrous glucose 5.6 mmol/l (equivalent to 1.0 g).

**Other ingredients:** Electrolyte solution (small chamber): Hydrochloric acid 25% (for pH adjustment), Water for Injections; Bicarbonate solution (large chamber): Carbon dioxide (for pH adjustment), Water for Injections

**Indications:** The ready-to-use solution is indicated for use in patients with acute renal failure of any origin who require continuous hemofiltration.

#### Contraindications

**Duosol® without Potassium Hemofiltration Solution/Duosol® with 2 mmol/l Potassium Hemofiltration Solution:** Specific contraindications related to the ready-to-use hemofiltration solution: Hypokalemia, metabolic alkalosis. General contraindications related to hemofiltration: Acute renal failure with pronounced hypercatabolism, where uremic symptoms can no longer be managed by hemofiltration; inadequate blood flow from the vascular access; any condition associated with increased risk of bleeding due to systemic anticoagulation.

#### Contraindications

**Duosol® with 4 mmol/l Potassium Hemofiltration Solution:** Specific contraindications related to the ready-to-use hemofiltration solution: Hypokalemia, metabolic alkalosis. General contraindications related to hemofiltration: Acute renal failure with pronounced hypercatabolism, where uremic symptoms can no longer be managed by hemofiltration; inadequate blood flow from the vascular access; any condition associated with increased risk of bleeding due to systemic anticoagulation.

**Adverse reactions:** No adverse reactions have been reported that could be directly associated with the bicarbonate-buffered hemofiltration solution. However, the following adverse effects may occur as a consequence of treatment or may be induced by the solution used: Hyperhydration or dehydration, electrolyte imbalance (e.g. hyperkalemia), hypophosphatemia, hyperglycemia, metabolic alkalosis, hypertension, hypotension, nausea, vomiting, muscle cramps.

**Warnings:** For intravenous use. Refer to the package leaflet. Keep out of reach of children.

**Date of information:** February 2019. **Pharmacy-only medicine.**

**Marketing Authorization Holder:** B. Braun Avitum AG, Schwarzenberger Weg 73-79, 34212 Melsungen, Germany

## Country-specific marketing authorization for Duosol. Further information on request.

### Indications

The ready-to-use solution is indicated for use in patients with acute renal failure of any cause requiring continuous haemofiltration.

### Contraindications

Ready-to-use solution dependent contraindications:

- Hypokalaemia (0 and 2 mmol/l potassium)
- Hyperkalaemia (4 mmol/l potassium)
- Metabolic alkalosis

### Hemofiltration dependent contra-indications:

- Acute renal failure with marked metabolic processes (hypercatabolism), if the uraemic symptoms cannot be corrected any longer by haemofiltration
- Inadequate blood flow from the vascular access
- All states with elevated hemorrhage risk on account of systemic anticoagulation.

### Pregnancy

There are no data from the use of Duosol® in pregnant woman or from animal studies. However, because all the ingredients of the solution for haemofiltration are physiological substances that serve to replace essential plasma components removed by haemofiltration, no risks for the unborn child are to be expected. The use of Duosol® may be considered during pregnancy, if necessary.

### Lactation

Because all the ingredients of the solution for haemofiltration are physiological substances that serve to replace essential plasma components removed by haemofiltration, no risks for the child are to be expected. The use of Duosol® may be considered during lactation, if necessary.

### Fertility

Because all the ingredients of the solution for haemofiltration are physiological substances that serve to replace essential plasma components removed by haemofiltration, no effects on fertility are to be expected.

### Undesirable effects

There have been no reports of adverse events or undesirable effects that might possibly be associated with the bicarbonate-buffered solution for hemofiltration. However, the following adverse reactions could result from the treatment or the solution used: Hyper- or dehydration, electrolyte disturbances (e.g. hypokalaemia, hyperkalaemia), hypophosphatemia, hyperglycaemia and metabolic alkalosis, nausea, vomiting, muscle cramps, hypertension and hypotension.

### Marketing authorization holder:

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34212 Melsungen, Germany