

Duosol[®]

Bicarbonate-buffered solution for hemofiltration



Avitum

HomeoSAFE
balanced by intelligence

B | BRAUN
SHARING EXPERTISE

Duosol®...

Knowledge serving health

As a supplier of dialysis and apheresis systems, B. Braun possesses a wealth of experience in the field of extracorporeal blood purification procedures. We have harnessed this knowledge to develop Duosol®, the bicarbonate-buffered replacement fluid for hemofiltration.

Duosol® is just one more way of proving how much we understand the demands you place on our designs and features. That is why we are committed to providing you with a product that is convincing throughout the process chain.

That product is Duosol®:

- A solution that guarantees an optimal therapeutic outcome.
- A bag material complying with high technical standards.
- A product design that simplifies handling.
- A packaging material that is environmentally friendly and economically profitable.

Innovative and efficient, this solution is a major step toward more improved therapies for acute renal failure. For patients and physicians alike.

Solutions of the future

In the treatment of patients with acute renal failure, the requirements are constantly changing. The bicarbonate buffered Duosol® is just the right solution to meet today's challenges by offering a physiological and directly available buffer that compensates for metabolic acidosis in patients with renal insufficiency.

Clinical studies on its safety and efficiency have demonstrated the decisive advantage of Duosol®: The rate of cardiovascular complications was markedly reduced.^{1,2}

Benefits

- Physiological buffer
- Optimal correction of metabolic acidosis
- Directly available buffer
- Fewer cardiovascular complications





...progress in renal
replacement therapy

Duosol® – bicarbonate for a good reason

Every challenging demands

In recent decades, major advantages have been achieved in the diagnosis and treatment of acute kidney failure.

Nevertheless, the gains in knowledge have not allowed us to reduce the mortality of the affected patients in a significantly meaningful way.

One reason for this fact is that the number of elderly patients is continually growing along with the complexity of their clinical pictures. Acute renal failure usually develops from multiple underlying diseases and, in many cases, is preceded by serious operations or sepsis.

The patients' severe problems are frequently exacerbated by pre-existing cardiovascular disease. The demands on therapy are raised, additionally worsening the prognosis.²

Such complexity demands solutions for treating acute renal failure that enable the physician to respond with the optimal therapy. Duosol® is just that kind of solution.



Personalizing therapies

The therapeutic objectives in acute renal failure are not only to achieve volume and uremic toxin removal, but also to compensate for metabolic acidosis. Accomplishment of these objectives also depends on the choice of the most suitable buffer for the patient.

There are clinical pictures where a bicarbonate-buffered solution is indispensable.

The limits of lactate-containing solutions are encountered when, concurrent with acute renal failure, other serious complications such as shock, sepsis, multiple organ failure, or severe cardiac insufficiency are manifest. In such instances, the patient's lactate metabolism may be limited either metabolically or by a lack of oxygen. Lactate acidosis can exacerbate any pre-existing acidosis even more.

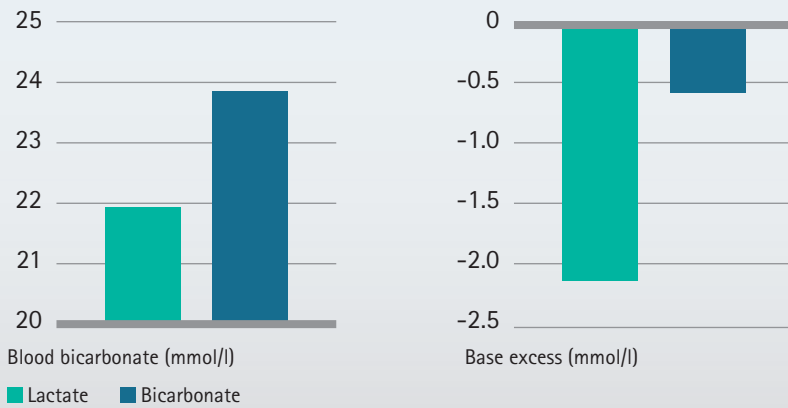
Moreover, persistent acidosis tends to worsen the prognosis of a patient with acute renal failure.⁴ For volume removal, continuous procedures achieve better cardiovascular stabilization and are, therefore, preferred over intermittent methods.

If necessary, high-volume hemofiltration can be utilized to enhance efficacy. In such instances where high amounts of bicarbonate in the filtrate are lost, the choice of a suitable buffer is vitally important.⁵ In this respect, too, Duosol® has proven to be a reliable and safe replacement fluid.



Duosol® – a safe solution for patients

Optimal correction of metabolic acidosis



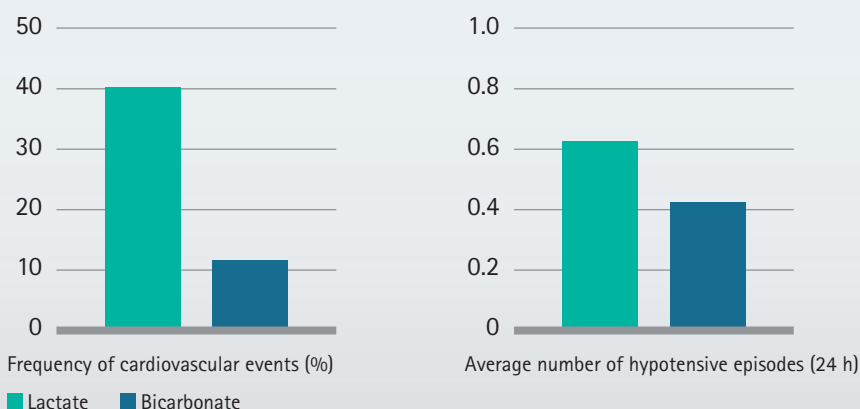
Achieving a balance

In one clinical study, Duosol® was compared with a lactate buffered solution on patients suffering from acute renal failure who were treated with continuous hemofiltration.² The bicarbonate-buffered solution normalized blood bicarbonate levels within the treatment period and considerably reduced the base excess.

The results clearly show that bicarbonate-buffered solutions achieve an adequate correction of metabolic acidosis in patients.

Duosol® leads to a direct elevation in the buffer capacity in the blood and thereby ensures a rapid and sustainable compensation of acidosis during renal replacement therapy. This feature is particularly beneficial when the use of lactate has come up against the limits outlined above.

Reduction of cardiovascular complications



Reducing complications

Alongside the positive effects, bicarbonate-buffered solutions have on acid-base metabolism, the study also demonstrated that treatment with replacement fluids buffered with bicarbonate significantly reduces the frequency of cardiovascular events in patients.

Similarly, the average number of hypotensive episodes was significantly lowered.²

The positive effects of bicarbonate-buffered solutions demonstrated here indicate that patients with cardiovascular instability or previous cardiovascular diseases can benefit particularly from these types of replacement fluid.

The development of Duosol® thus represents a decisive step forward in the treatment of acute renal failure.

A new generation of bags...

Utilizing experience

With Duosol®, B. Braun has succeeded in providing a bicarbonate solution in a double-chamber bag with compelling features: The solution's composition and therapeutic effect in combination with the system's handling and material properties.

Implementing innovation

One aim in developing the new product was to create not only an optimal solution but also a smart and contemporary system that features a high degree of biocompatibility. The new generation of bags is PVC-free. This means that the use of softeners and latex components has been eliminated entirely.

System features

- Biocompatible bag material
- Intelligent product design
- Less packaging means less waste

In order to prevent CO₂ from escaping from the solution and resulting in a shift in pH it has been packaged in a gas impermeable material. As a result, Duosol® gives you an excellent hemofiltration solution in a handy double-chamber bag made of innovative materials.

Acting sustainably

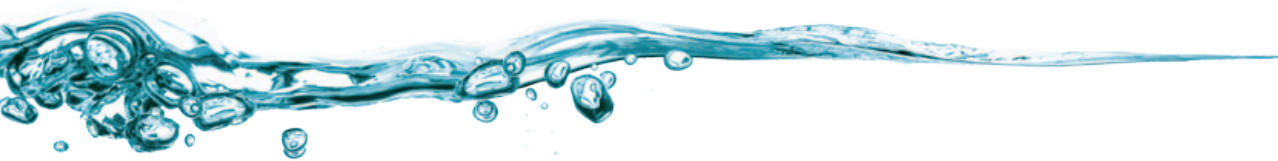
Thanks to its low density and foil thickness, the new bag material only generates around half of the amount of waste of conventional bag materials. Moreover, its combustion produces only carbon dioxide and water without any other residues.

The innovative material completes the optimized system for the technologically demanding manufacturing of bicarbonate-buffered solutions.





...means progress for patients
and the environment



...saves time and energy

Streamlining work routines

The treatment and care of the critically ill requires everybody's full and undivided attention.

For that reason, we are committed to designing products that streamline work routines.

The Duosol®-double-chamber bag lets the user concentrate on the really important things.

Enhancing efficiency

With the practical 5-liter double-chamber bag, much less time is needed for preparation and changeovers:

- The double-chamber bag helps save time and energy during preparation and changeovers.
- Solutions can be mixed easily and reliably through the sealing seam that opens up along the entire length of the bag.
- 5-liter bag extends changeover intervals.



1. Open the bag's outer packaging on the side where the hanger holes are located and tear off the outer foil completely.



2. Flip up the bag and place it on a solid surface.



3. Press the corners of the small chamber with both hands until the sealing seam between the two chambers starts opening up.



4. Then, press on the large chamber with both hands until the sealing seam is opened up entirely. After mixing the solution is ready for use.



Composition of solutions

Composition of the ready-to-use solutions

Duosol®	Na ⁺ mmol/l	K ⁺ mmol/l	Ca ⁺⁺ mmol/l	Mg ⁺⁺ mmol/l	Cl mmol/l	HCO ₃ ⁻ mmol/l	Glucose mmol/l	Theoret. osmolarity mOsm/l
without potassium	140	0	1.5	0.5	109	35.0	5.5	292
with 2 mmol/l potassium	140	2	1.5	0.5	111	35.0	5.5	296
with 4 mmol/l potassium	140	4	1.5	0.5	113	35.0	5.5	300

Packaging type: 1 box contains 2 bags, pallet assembly: 50 boxes

Composition of the unmixed solutions

Active substances g/l	Duosol® without potassium		Duosol® with 2 mmol/l potassium		Duosol® with 4 mmol/l potassium	
	large chamber 4445 ml	small chamber 555 ml	large chamber 4445 ml	small chamber 555 ml	large chamber 4445 ml	small chamber 555 ml
Sodium chloride	6.18	4.21	6.18	4.21	6.18	4.21
Potassium chloride	-	-	-	1.34	-	2.68
Calciumchloride dihydrate	-	1.98	-	1.98	-	1.98
Magnesium chloride hexahydrate	-	0.91	-	0.91	-	0.91
Glucose monohydrate	-	9.90	-	9.90	-	9.90
Sodium hydrogen carbonate	3.59	-	3.59	-	3.59	-

Other constituents:

Electrolyte solution (small chamber): hydrochloric acid 25% for adjusting the pH, water for injections

Bicarbonate solution (large chamber): carbon dioxide for adjusting the pH, water for injections

Country-specific marketing authorization. Further information on request.

<p>Indications</p> <p>The ready-to-use solution is indicated for the treatment by continuous hemofiltration of intensive care unit patients with acute renal failure of any origin.</p> <p>Contraindications</p> <p>Ready-to-use solution dependent contra-indications:</p> <ul style="list-style-type: none"> ▪ Hypokalaemia (Duosol® without potassium, Duosol® with 2 mmol/l potassium) ▪ Hyperkalaemia (Duosol® with 4 mmol/l potassium) ▪ Metabolic alkalosis <p>Hemofiltration dependent contraindications:</p> <ul style="list-style-type: none"> ▪ Acute renal failure with marked metabolic processes (hypercatabolism), if the uremic symptoms cannot be corrected any longer by hemofiltration ▪ Inadequate blood flow from the vascular access ▪ All states with elevated hemorrhage risk on account of systemic anticoagulation. 	<p>Use during pregnancy:</p> <p>There are, at present, no reports of clinical experience. The bicarbonate-buffered solution for hemofiltration may only be administered after consideration of the potential risks and benefits for mother and child.</p> <p>Use during lactation:</p> <p>No special restrictions.</p> <p>Undesirable effects</p> <p>Side effects can result from the treatment or the solution for hemofiltration used. Bicarbonate-buffered hemofiltration solutions are generally well tolerated. There have been no reports of adverse events or side effects that might possibly be associated with the bicarbonate-buffered solution for hemofiltration.</p>	<p>However, the following side effects are conceivable:</p> <p>Hyper- or hypohydration, electrolyte disturbances (e.g. hypokalaemia with Duosol® without potassium and Duosol® with 2 mmol/l potassium; hyperkalaemia with Duosol® with 4 mmol/l potassium), hypophosphatemia, hyperglycemia and metabolic alkalosis.</p> <p>The following side effects may occur during treatment: nausea, vomiting, muscle cramps, and hypotension.</p> <p>Marketing authorization holder:</p> <p>B. Braun Avitum AG Am Buschberg 1 34212 Melsungen Germany</p>
---	---	--

References

- ¹ Kierdorf HP, Leue C, Arns S. Lactate- or bicarbonate-buffered solutions in continuous extracorporeal renal replacement therapies. *Kidney Int* 1999; 56 (Suppl. 72): 32-36.
- ² Barenbrock M, Hausberg M, Matzkies F, de la Motte S, Schaefer RM. Effects of bicarbonate- and lactatebuffered replacement fluids on cardiovascular outcome in CVVH patients. *Kidney Int* 2000; 58 (4): 1751-1557.
- ³ Davenport A, Will EJ, Davison AM. Hyperlactataemia and metabolic acidosis during haemofiltration using lactate-buffered fluids. *Nephron* 1991; 59 (3): 461-465.
- ⁴ Thomas AN, Guy JM, Kishen R, Geraghty IF, Bowles BJ, Vadgama P. Comparison of lactate and bicarbonate buffered haemofiltration fluids: use in critically ill patients. *Nephrol Dial Transplant* 1997; 12 (6): 1212-1217.
- ⁵ Cole L, Bellomo R, Baldwin I, Hayhoe M, Ronco C. The impact of lactate-buffered high-volume hemofiltration on acid-base balance. *Intensive Care Med* 2003; 29: 1113-1120.

