multiBic
potassium-free

Package Insert
Solution for haemodialysis/ haemofiltration

ملٹی بِک پوٹاشیم فری محلول برائے ہیموڈیالیسس/ہیموفلٹریشن

HK PK

What is in this leaflet

1. What multiBic potassium-free is and what it is used for
2. What you need to know before you use multiBic potassium-free
3. How to use multiBic potassium-free
4. Possible side effects
5. How to store multiBic potassium-free
6. Contents of the pack and other information

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

1. What multiBic potassium-free is and what it is used for

multiBic potassium-free is a continuous renal replacement therapy solution for removal of waste products from the body in people with kidney disease. It is used in patients with kidney injury and also for the treatment of poisoning. The type of solution you are given depends on the amount of potassium (a salt) in your blood. Your doctor will check your potassium levels regularly.

2. What you need to know before you use multiBic potassium-free

Do not use multiBic potassium-free if

- you are allergic to any of the active substances or any of the other ingredients of this medicine (listed in section 6)
- you have hypokalaemia (your potassium level is very low)
- you have metabolic alkalosis (a condition where there is too much bicarbonate in the blood)
- you cannot achieve a sufficient blood flow through the haemofilter (filter used in the blood filtration)
- you have a high risk of bleeding related to medications required to prevent clotting in the haemofilter.

Warnings and precautions

Talk to your doctor before using multiBic potassium-free

- **Must be used only after mixing the two solutions in the double chamber (two-compartment) bag.**
- Must not be used under any circumstances below room temperature.
- The tubing lines used to apply the ready-to-use solution should be inspected every 30 minutes. If precipitate (solid matter) is observed within these tubing lines, bag and tubing lines must be replaced immediately and the patient carefully monitored.
- Your doctor will check your hydration status (the amount of water in your body), the levels of potassium, sodium, other salts, certain waste products, and your blood sugar levels. Your doctor also might advise you about your diet.

Children

Use of multiBic potassium-free has not been established in children.

Other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Following interactions are conceivable:

- toxic effects of digitalis (medicine for treatment of heart disease)
- electrolyte substitutions, parenteral nutrition (intravenous feeding) and other infusions treatment. Their effect on blood serum concentration and fluid status must be considered when using this therapy.
- This therapy may reduce the blood concentration of medicinal products. Dose adjustment may be required.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before starting treatment with this medicine.

There are no or limited amount of data on the use of multiBic potassium-free during pregnancy and breast-feeding.

This medicine should only be used during pregnancy if your doctor considers treatment necessary.

Breast-feeding is not recommended during treatment with multiBic potassium-free.

The following information is intended for healthcare professionals only:

1000 ml of the ready-to-use solution contain:

	multiBic potassium-free	Unit
Sodium chloride	6.136	g
Sodium hydrogen carbonate	2.940	g
Calcium chloride dihydrate	0.2205	g
Magnesium chloride hexahydrate	0.1017	g
Glucose monohydrate (Glucose)	1.100 (1.000)	g

K^+	-
Na^+	140 mmol/l
Ca^{2+}	1.5 mmol/l
Mg^{2+}	0.50 mmol/l
Cl^-	109 mmol/l
HCO_3^-	35 mmol/l
Glucose	5.55 mmol/l
pH ≈ 7.4	

Theoretical osmolarity (Theor. osmolar.) 292 mOsm/l

Do not use unless the ready-to-use solution is clear and colourless and the bag and connectors are undamaged.

For single use only. Any unused solution must be discarded.

Must be used by means of metering pumps.

Instructions for use

The solution for haemodialysis/haemofiltration should be administered in three steps:

1. Removal of the protective foil and careful inspection of the bag

The protective foil should only be removed immediately before administration. Plastic containers may occasionally be damaged during transport from the manufacturer to the clinic or within the clinic itself. This can lead to contamination and microbiological or fungal growth in the solutions. Therefore, careful visual inspection of the bag and of the solutions before use is necessary. Particular attention should be paid to even the slightest damage to the closure of the bag, the welded seam and the corners of the bag.

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3. How to use multiBic potassium-free

multiBic potassium-free will be given in a hospital or clinic. Your doctor will know how to use this medicine.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects of multiBic potassium-free include:

- nausea (feeling sick)
- vomiting (being sick)
- muscle cramps
- changes in blood pressure

Some side effects might be caused by too much or too little fluid. These are:

- shortness of breath
- swelling of the ankles and legs
- dehydration (e.g. dizziness, muscle cramps, feeling thirsty)
- blood disorders (e.g. abnormal salt concentrations in your blood)

The exact frequency of such events is not known (cannot be estimated from the available data).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store multiBic potassium-free

Do not store below +4 °C. Do not store above +30 °C.

請勿將產品儲存於溫度攝氏 30 ° C 以上及 4 ° C 以下。

Keep this medicine out of sight and reach of children.

Storage conditions after mixing of the two compartments: The ready-to-use solution should not be stored above +30 °C and must be used within a maximum of 48 hours. Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

6. Content of the pack and other information

What multiBic potassium-free contains

- The active substances are sodium chloride, sodium hydrogen carbonate, calcium chloride dihydrate, magnesium chloride hexahydrate, glucose monohydrate.
- The other ingredients are water for injections, hydrochloric acid 25 %, carbon dioxide and sodium dihydrogen phosphate dihydrate.

What multiBic potassium-free looks like and contents of the pack

multiBic potassium-free is delivered in a double chamber bag (two-compartments containing different solutions). Mixing of the solutions in both compartments results in the ready-to-use solution.

Each bag contains 5000 ml solution in total. The ready-to-use solution is clear and colourless.

Each bag is equipped with a HF-connector, a Luer-lock-connector and an injection port, and is covered by a protective foil.

Pack size:

2 bags of 5000 ml HK-57338

Manufacturer

Fresenius Medical Care Deutschland GmbH,
Frankfurter Straße 6-8, 66606 St. Wendel, Germany

For Pakistan:
Imported and Marketed by:

Fresenius Medical Care Pakistan Pvt. Ltd.
TAMC, First Floor 27-C III, M.M. Alam Road, Gulberg III, Lahore 54660, Pakistan

Registration Number: 114282.

۴ ڈگری سینٹی سے کم اور ۳۰ ڈگری سینٹی سے زیادہ درجہ حرارت میں سٹور نہ کریں۔
بچوں کی نظر اور پہنچ سے دور رکھیں۔

This leaflet was last revised in June 2021.

Information for healthcare professionals only see end of this package leaflet.

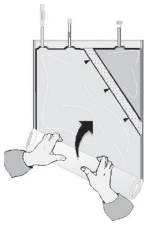
2. Mixing of the two compartments

The two solutions should be mixed immediately before use to produce a ready-to-use solution.

A)

Unfold the small compartment.

B)



Roll up the solution bag starting from the corner opposite the small compartment...

C)

... until the peel seam between both compartments has opened along its entire length and the solutions from both compartments are mixed.

After mixing both compartments, it must be checked, that the peel seam is completely open, that the mixed solution is clear and colourless and that the bag is not leaking.

3. Application of the ready-to-use solution

The ready-to-use solution must be used immediately, but within a maximum of 48 hours after mixing.

Any admixture to the ready-to-use solution must only be done after the ready-to-use solution has been thoroughly mixed. After such an admixture, the ready-to-use solution must again be thoroughly mixed prior to use.

Admixtures of sodium chloride solution (up to 30 %) or alternatively water for injection are compatible with this medicinal product and can be used to adjust the sodium concentration if needed in order to limit the speed of sodium concentration changes in case of severe hyper- or hyponatremia. For details please refer to the Summary of Product Characteristics.

If not otherwise prescribed, the ready-to-use solution should be warmed immediately before infusion into the patient to 36.5 °C – 38.0 °C. The exact temperature must be selected depending on clinical requirements and the technical equipment used.

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multiBic
potassium-free

Haemodialysis/haemofiltration solution
Package Insert
Solution for haemodialysis/ haemofiltration

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SG

1. What multiBic potassium-free is and what it is used for

multiBic potassium-free is a continuous renal replacement therapy solution for removal of waste products from the body in people with kidney disease. It is used in patients with kidney injury and also for the treatment of poisoning. The type of solution you are given depends on the amount of potassium (a salt) in your blood. Your doctor will check your potassium levels regularly.

2. What you need to know before you use multiBic potassium-free

Do not use multiBic potassium-free if

- you are allergic to any of the active substances or any of the other ingredients of this medicine (listed in section 6)
- you have hypokalaemia (your potassium level is very low)
- you have metabolic alkalosis (a condition where there is too much bicarbonate in the blood)
- you cannot achieve a sufficient blood flow through the haemofilter (filter used in the blood filtration)
- you have a high risk of bleeding related to medications required to prevent clotting in the haemofilter.

Warnings and precautions

Talk to your doctor before using multiBic potassium-free

- **Must be used only after mixing the two solutions in the double chamber (two-compartment) bag.**
- Must not be used under any circumstances below room temperature.
- The tubing lines used to apply the ready-to-use solution should be inspected every 30 minutes. If precipitate (solid matter) is observed within these tubing lines, bag and tubing lines must be replaced immediately and the patient carefully monitored.
- Your doctor will check your hydration status (the amount of water in your body), the levels of potassium, sodium, other salts, certain waste products, and your blood sugar levels. Your doctor also might advise you about your diet.

Children

Use of multiBic potassium-free has not been established in children.

Other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Following interactions are conceivable:

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If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before starting treatment with this medicine.

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Breast-feeding is not recommended during treatment with multiBic potassium-free.

The following information is intended for healthcare professionals only:

1000 ml of the ready-to-use solution contain:

	multiBic potassium-free	Unit
Sodium chloride	6.136	g
Sodium hydrogen carbonate	2.940	g
Calcium chloride dihydrate	0.2205	g
Magnesium chloride hexahydrate	0.1017	g
Glucose monohydrate (Glucose)	1.100 (1.000)	g

K^+	-
Na^+	140 mmol/l
Ca^{2+}	1.5 mmol/l
Mg^{2+}	0.50 mmol/l
Cl^-	109 mmol/l
HCO_3^-	35 mmol/l
Glucose	5.55 mmol/l
pH ≈ 7.4	

Theoretical osmolarity (Theor. osmolar.) 292 mOsm/l

Do not use unless the ready-to-use solution is clear and colourless and the bag and connectors are undamaged.

For single use only. Any unused solution must be discarded.

Must be used by means of metering pumps.

Instructions for use

The solution for haemodialysis/haemofiltration should be administered in three steps:

1. Removal of the protective foil and careful inspection of the bag

The protective foil should only be removed immediately before administration. Plastic containers may occasionally be damaged during transport from the manufacturer to the clinic or within the clinic itself. This can lead to contamination and microbiological or fungal growth in the solutions. Therefore, careful visual inspection of the bag and of the solutions before use is necessary. Particular attention should be paid to even the slightest damage to the closure of the bag, the welded seam and the corners of the bag.

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3. How to use multiBic potassium-free

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4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects of multiBic potassium-free include:

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Reporting of side effects

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By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store multiBic potassium-free

Do not store below +4 °C. Do not store above +30 °C.

Keep this medicine out of sight and reach of children.

Storage conditions after mixing of the two compartments: The ready-to-use solution should not be stored above +30 °C and must be used within a maximum of 48 hours. Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

6. Content of the pack and other information

What multiBic potassium-free contains

- The active substances are sodium chloride, sodium hydrogen carbonate, calcium chloride dihydrate, magnesium chloride hexahydrate, glucose monohydrate.
- The other ingredients are water for injections, hydrochloric acid 25 %, carbon dioxide and sodium dihydrogen phosphate dihydrate.

What multiBic potassium-free looks like and contents of the pack

multiBic potassium-free is delivered in a double chamber bag (two-compartments containing different solutions). Mixing of the solutions in both compartments results in the ready-to-use solution.

Each bag contains 5000 ml solution in total. The ready-to-use solution is clear and colourless.

Each bag is equipped with a HF-connector, a Luer-lock-connector and an injection port, and is covered by a protective foil.

Pack size:

2 bags of 5000 ml

Manufacturer

Fresenius Medical Care Deutschland GmbH,
Frankfurter Straße 6-8, 66606 St. Wendel, Germany

Imported and Distributed by:

Fresenius Medical Care Singapore Pte Ltd. Singapore

This leaflet was last revised in June 2021.

Information for healthcare professionals only see end of this package leaflet.

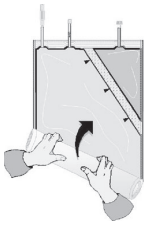
2. Mixing of the two compartments

The two solutions should be mixed immediately before use to produce a ready-to-use solution.

A)

Unfold the small compartment.

B)



Roll up the solution bag starting from the corner opposite the small compartment...

C)

… until the peel seam between both compartments has opened along its entire length and the solutions from both compartments are mixed.

After mixing both compartments, it must be checked, that the peel seam is completely open, that the mixed solution is clear and colourless and that the bag is not leaking.

3. Application of the ready-to-use solution

The ready-to-use solution must be used immediately, but within a maximum of 48 hours after mixing.

Any admixture to the ready-to-use solution must only be done after the ready-to-use solution has been thoroughly mixed. After such an admixture, the ready-to-use solution must again be thoroughly mixed prior to use.

Admixtures of sodium chloride solution (up to 30 %) or alternatively water for injection are compatible with this medicinal product and can be used to adjust the sodium concentration if needed in order to limit the speed of sodium concentration changes in case of severe hyper- or hyponatremia. For details please refer to the Summary of Product Characteristics.

If not otherwise prescribed, the ready-to-use solution should be warmed immediately before infusion into the patient to 36.5 °C – 38.0 °C. The exact temperature must be selected depending on clinical requirements and the technical equipment used.

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multiBic
potassium-free

Package Insert
Solution for haemodialysis/ haemofiltration

1. Product Name

multiBic potassium-free solution for haemodialysis/ haemofiltration

2. Name and Strength of Active Ingredient(s)

Active substance:

1000 ml of the ready-to-use solution contain:

	multiBic potassium-free
Potassium chloride	**-**
Sodium chloride	6.136 g
Sodium hydrogen carbonate	2.940 g
Calcium chloride dihydrate	0.2205 g
Magnesium chloride hexahydrate	0.1017 g
Glucose monohydrate (Glucose)	1.100 g (1.000 g)

	multiBic potassium-free
K^+	**-**
Na^+	140 mmol/l
Ca^{2+}	1.5 mmol/l
Mg^{2+}	0.50 mmol/l
Cl^-	109 mmol/l
HCO_3^-	35 mmol/l
Glucose	5.55 mmol/l

The other ingredients are water for injections, hydrochloric acid 25 %, carbon dioxide, and sodium dihydrogen phosphate dihydrate.

3. Product Description

multiBic potassium-free is a solution for haemodialysis/ haemofiltration. The ready-to-use solution is clear and colourless.

Theoretical osmolarity: 292 mOsm/l pH≈7.4

4. Pharmacodynamics/ Pharmacokinetics

4.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Haemofiltrates

ATC code: B05Z B

Mechanism of action

Basic principles of haemodialysis, haemofiltration and haemodiafiltration:

During haemofiltration water and solutes such as uremic toxins, electrolytes, and bicarbonate are removed from the blood by ultrafiltration. The ultrafiltrate is replaced by a solution for haemofiltration, with a balanced electrolyte and buffer composition.

During haemodialysis, water and solutes such as uremic toxins, electrolytes, bicarbonate and other small molecules are exchanged between the patient's blood and the solution for haemodialysis by diffusion. The direction and the magnitude of the diffusion process depend on the relevant concentration gradients between the blood and the solution for haemodialysis.

In haemodiafiltration, the underlying principles of haemofiltration and haemodialysis are combined.

This medicinal product is a bicarbonate-buffered solution for intravenous administration or for use as haemodialysis solution for the balancing of water and electrolyte removal during continuous renal replacement therapies which are applied, e.g. in the treatment of acute kidney injury.

The electrolytes Na^+, K^+, Mg^{2+}, Ca^{2+}, Cl^-, and bicarbonate are essential for the maintenance and correction of fluids and electrolyte homeostasis (blood volume, osmotic equilibrium, acid-base balance).

Paediatric population

There is no clinical experience on the use of this product in children. This medicinal product is not recommended for use in children until further data become available (see sections 7 and 9).

4.2 Pharmacokinetic Properties

This medicinal product must only be administered intravenously or used as haemodialysis solution.

Distribution/ Biotransformation/ Elimination

The distribution of electrolytes and bicarbonate is regulated in accordance with requirements and the metabolic status and residual renal function. The active substances of this medicinal product are not metabolised except for glucose. The elimination of water and electrolytes depends on cellular requirements, the metabolic status, the residual renal function, and on other routes of fluid losses (e.g., gut, lung, and skin).

5. Indication

multiBic potassium-free is indicated for intravenous use as substitution solution in haemofiltration and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration.

For use in patients

- with acute kidney injury requiring continuous renal replacement therapy: continuous haemodialysis, haemofiltration or haemodiafiltration treatments.
- with chronic kidney disease in whom a transient treatment is indicated, e.g. during the stay on an intensive care unit.
- when continuous renal replacement therapy is indicated as part of the treatment of an intoxication with water soluble, filterable/dialyzable toxins.

multiBic potassium-free is indicated in adults.

6. Recommended Dose

Continuous renal replacement therapy including the prescription of this medicinal product should be performed under the direction of a physician with experience in these treatments.

7. Mode of Administration

In acute kidney injury, a continuous treatment with a dose of 2000 ml/h multiBic potassium-free is appropriate in adults with a body weight of 70 kg to remove metabolic waste products depending on the metabolic status of the patient. The dose should be adapted to the body size of the patient.

In patients with chronic kidney disease, unless clinically indicated otherwise, the dose of multiBic potassium-free should be at least one third of the body weight per session with three sessions applied per week. Increasing the volume applied per week or distributing this weekly volume to more than 3 treatments per week can be required.

The dose and the duration of haemodialysis, haemofiltration or haemodiafiltration necessary in treatment of acute states of intoxication depends on the toxin and its concentration and the severity of clinical symptoms and has to be clinically decided on the individual patient's condition.

A maximum dose of 75 litre per day is recommended.

Paediatric population

The safety and efficacy of multiBic potassium-free in children have not yet been established (see sections 9 and 4.1).

Method of administration

For intravenous use and haemodialysis.

Do not use unless the ready-to-use solution is clear and colourless and the bag and connectors are undamaged.

For single use only. Any unused solution must be discarded.

Must be used by means of metering pumps.

Instructions for use

The solution for haemodialysis/haemofiltration should be administered in three steps:

1. Removal of the protective foil and careful inspection of the bag

The protective foil should only be removed immediately before administration.

Plastic containers may occasionally be damaged during transport from the manufacturer to the clinic or within the clinic itself. This can lead to contamination and microbiological or fungal growth in the solutions. Therefore, careful visual inspection of the bag and the solutions before mixing is necessary. Particular attention should be paid to even the slightest damage to the closure, the welded seam and the corners of the bag in view of a possible contamination.

2. Mixing of the two compartments

The two-compartment-bag - the bicarbonate and the electrolytes including glucose compartments - are mixed immediately before use to obtain a ready-for-use solution.

A)

Unfold the small compartment.

B)

Roll up the solution bag starting from the corner opposite the small compartment…

C)

… until the peel seam between both compartments has opened along its entire length and the solutions from both compartments are mixed.

After mixing both compartments, it must be checked, that the peel seam is completely open, that the mixed solution is clear and colourless and that the bag is not leaking.

3. Application of the ready-to-use solution

The ready-to-use solution must be used immediately, but within a maximum of 48 hours after mixing.

Any admixture to the ready-to-use solution must only be done after the ready-to-use solution has been thoroughly mixed. After such an admixture, the ready-to-use solution should again be thoroughly mixed prior to use.

Admixtures of sodium chloride solution (concentration between 3 % and 30 % sodium chloride; up to 250 mmol sodium chloride per 5 litre multiBic solution) and water for injection (up to 1250 ml per 5 litre multiBic solution) are compatible with this medicinal product.

If not otherwise prescribed, the ready-to-use solution should be warmed immediately before use to 36.5 °C – 38.0 °C. The exact temperature must be selected depending on clinical requirements and the technical equipment used.

No special requirements for disposal. This medicinal product must not be mixed with other medicinal products except those mentioned above.

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8. Contraindication

Solution related contraindications:

- Hypersensitivity to the active substances or to any of the excipients listed in section 2
- Hypokalaemia
- Metabolic alkalosis

Contraindications for use of the technical procedure itself:

- Inadequate blood flow from vascular access.
- If there is a high risk of haemorrhage on account of systemic anticoagulation.

9. Warnings and Precautions

Use only after mixing of the two solutions.

multiBic potassium-free should be warmed prior to use with appropriate equipment to approximately body temperature and must not be used under any circumstances below room temperature.

The warming of the ready-to-use solution to approximately body temperature must be carefully controlled verifying that the ready-to-use solution is clear and without particles.

During application of the ready-to-use solution, white calcium carbonate precipitation has been observed in the tubing lines in rare cases, particularly close to the pump unit and the heating unit warming the ready-to-use solution.

Precipitations particularly can occur if the temperature of the ready-to-use solution at the inlet of the pump unit is already higher than 30 °C.

Therefore, the ready-to-use solution in the tubing lines must be closely visually inspected every 30 min during continuous renal replacement therapy in order to ensure, that the solution in the tubing system is clear and free from precipitate. Precipitations may occur also with substantial delay after start of treatment.

If precipitate is observed, the ready-to-use solution and the tubing lines used for continuous renal replacement therapy must be replaced immediately and the patient carefully monitored.

The serum potassium concentration must be checked regularly before and during continuous renal replacement therapy. The potassium status of the patient and its trend during the treatment must be considered:

In case of hypokalaemia supplementation of potassium and / or changing to a solution for haemodialysis/ haemofiltration with higher potassium concentration may be required.

In case of hyperkalaemia an increase in the applied dose and / or change to a solution for haemodialysis/ haemofiltration with a lower potassium concentration may be indicated as well as usual measures of intensive care medicine.

The serum sodium concentration must be checked regularly before and during use of this solution for haemodialysis/haemofiltration to control risks related to hypo/hypernatraemia. The solution for haemodialysis/ haemofiltration may be diluted with an adequate amount of water for injections or concentrated sodium chloride solution may be added if required. The speed of desired normalisation must then be carefully planned to avoid adverse reactions due to rapid changes in serum sodium concentration.

In addition, the following parameters must be monitored before and during continuous renal replacement therapy: Serum calcium, serum magnesium, serum phosphate, serum glucose, acid-base status, levels of urea and creatinine, body weight and fluid balance (for the early recognition of hyper- and dehydration).

Clinically important substances may be removed with the haemodialysis, haemofiltration and haemodiafiltration treatment and are not supplemented with this medicinal product. This removal of important nutrients must be compensated by adequate nutrition, nutritional supplements, or an adapted parenteral nutrition.

Paediatric population

There is no clinical experience on the use of this product in children. This medicinal product is not recommended for use in children until further data become available (see sections 7 and 4.1).

10. Interactions With Other Medicaments

No interaction studies have been performed.

The correct dose of multiBic potassium-free and strict monitoring of clinical chemistry parameters and vital signs will avoid risks related to interactions with other medicinal products.

The following interactions are conceivable:

- Toxic effects of digitalis may be masked by hyperkalaemia, hypermagnesaemia and hypocalcaemia. The correction of these electrolytes by continuous renal replacement therapy may precipitate signs and symptoms of digitalis toxicity, e.g. cardiac arrhythmia.
- Electrolyte substitutions, parenteral nutrition and other infusions usually given in intensive care medicine interact with the serum composition and the fluid status of the patient. This must be considered during application of continuous renal replacement therapy.
- Continuous renal replacement therapy may reduce the blood concentration of drugs, especially of drugs with a low protein binding capacity, with a small distribution volume, with a molecular weight below the cut-off of the haemofilter and of medicinal products adsorbed to the haemofilter. An appropriate revision of the dose of such medicinal products may be required.

11. Pregnancy and Lactation

There are no or limited amount of data from the use of multiBic potassium-free in pregnant women. Animal studies are insufficient with respect to reproductive toxicity.

multiBic potassium-free should not be used during pregnancy unless the clinical condition of the woman requires continuous renal replacement therapy.

There is insufficient information on the excretion of multiBic potassium-free active substances/metabolites in human milk.

Breastfeeding is not recommended during treatment with multiBic potassium-free.

12. Undesirable Effects

Adverse reactions may result from the treatment mode itself or may be induced by this medicinal product:

Gastrointestinal disorders - nausea, vomiting

Vascular disorders - hypertension, hypotension

Musculoskeletal and connective tissue disorders - muscle cramps

The following adverse reaction can be anticipated for the treatment mode:

Metabolism and nutrition disorders - hyper- or hypohydration, electrolyte disturbances (e.g., hypokalaemia), hypophosphataemia, hyperglycaemia, and metabolic alkalosis.

The exact frequency of such events is not known (cannot be estimated from the available data).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

13. Overdose and treatment

After use of recommended doses no reports of emergency situations have arisen; moreover, the administration of this medicinal product can be discontinued at any time. If fluid balance is not accurately calculated and monitored, hyperhydration or dehydration may occur, with the resultant associated circulatory reactions. These may be manifest through changes in blood pressure, central venous pressure, heart rate, and pulmonary arterial pressure. In cases of hyperhydration congestive cardiac failure and/or pulmonary congestion may be induced.

In cases of hyperhydration, net fluid removal should be increased on the device used for continuous renal replacement therapy. In cases of marked dehydration, net fluid removal by the device used for continuous renal replacement therapy should be decreased or discontinued; alternatively, fluid resuscitation can be applied to restore the hydration status.

If too large volume is applied, this may result in disturbances of electrolyte concentrations and the acid-base-balance, e. g. an overdose of bicarbonate may occur if an inappropriate large volume of the solution for haemodialysis/haemofiltration is infused /administered. This could possibly lead to metabolic alkalosis, decrease of ionized calcium, or tetany.

14. Storage Condition

Do not store below +4 °C. Do not store above +30 °C.

Keep this medicine out of sight and reach of children.

Shelf life: 2 years

Chemical and physical in-use stability of the ready-to-use solution has been demonstrated for 48 hours at 30 °C. It is not recommended to store the ready-to-use solution longer than 48 hours including duration of treatment or at a temperature higher than 30 °C prior to the inlet of the pump unit.

From a microbiological point of view, once connected to the haemodialysis, haemofiltration or haemodiafiltration circuit, and as hydrogen carbonate is present, the product shall be used immediately.

15. Dosage Forms and packaging available

Double chamber bag with 4750 ml (alkaline hydrogen carbonate solution) + 250 ml (acidic electrolyte, glucose solution) = 5000 ml (ready-to-use solution).

The foil used for the bag is made of polyethylene-terephthalate, SiOx, polyamide, and polyolefine.

Each bag is equipped with a HF-connector, a Luer-lock-connector and an injection port, and is covered by a protective foil.

Each bag contains 5000 ml solution in total.

Pack size: 2 bags of 5000 ml.

16. Manufacturer/Product Registration Holder

Manufacturer

Fresenius Medical Care Deutschland GmbH Frankfurter Straße 6-8,
66606 St. Wendel, Germany

For Malaysia:

Product Registration Holder

Fresenius Medical Care Malaysia Sdn.Bhd.,
2nd Floor, Axis Technology Centre,
Lot 13, Jalan 51A/225,
46100 Petaling Jaya, Selangor, Malaysia.
Reg. No.: MAL17085034AZ
Jauhi daripada kanak-kanak.
Controlled Medicine/ Ubat Terkawal.

17. Date of Revision of Package Insert

The insert was last revised in September 2025.

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multiBic

potassium-free

Haemodialysis/haemofiltration solution

Rx

Package Insert
Solution for haemodialysis/ haemofiltration

1. Product Name

multiBic potassium-free solution for haemodialysis/ haemofiltration

2. Name and Strength of Active Ingredient(s)

Active substance:

1000 ml of the ready-to-use solution contain:

	multiBic potassium-free
Potassium chloride	**-**
Sodium chloride	6.136 g
Sodium hydrogen carbonate	2.940 g
Calcium chloride dihydrate	0.2205 g
Magnesium chloride hexahydrate	0.1017 g
Dextrose monohydrate (Glucose)	1.100 g (1.000 g)

	multiBic potassium-free
K^+	**-**
Na^+	140 mmol/l
Ca^{2+}	1.5 mmol/l
Mg^{2+}	0.50 mmol/l
Cl^-	109 mmol/l
HCO_3^-	35 mmol/l
Glucose	5.55 mmol/l

The other ingredients are water for injections, hydrochloric acid 25 %, carbon dioxide, and sodium dihydrogen phosphate dihydrate.

3. Product Description

multiBic potassium-free is a solution for haemodialysis/ haemofiltration. The ready-to-use solution is clear and colourless.

Theoretical osmolarity: 292 mOsm/l pH≈7.4

4. Pharmacodynamics/ Pharmacokinetics

4.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Haemofiltrates

ATC code: B05Z B

Mechanism of action

Basic principles of haemodialysis, haemofiltration and haemodiafiltration:

During haemofiltration water and solutes such as uremic toxins, electrolytes, and bicarbonate are removed from the blood by ultrafiltration. The ultrafiltrate is replaced by a solution for haemofiltration, with a balanced electrolyte and buffer composition.

During haemodialysis, water and solutes such as uremic toxins, electrolytes, bicarbonate and other small molecules are exchanged between the patient's blood and the solution for haemodialysis by diffusion. The direction and the magnitude of the diffusion process depend on the relevant concentration gradients between the blood and the solution for haemodialysis.

In haemodiafiltration, the underlying principles of haemofiltration and haemodialysis are combined.

This medicinal product is a bicarbonate-buffered solution for intravenous administration or for use as haemodialysis solution for the balancing of water and electrolyte removal during continuous renal replacement therapies which are applied, e.g. in the treatment of acute kidney injury.

The electrolytes Na^+, K^+, Mg^{2+}, Ca^{2+}, Cl^-, and bicarbonate are essential for the maintenance and correction of fluids and electrolyte homeostasis (blood volume, osmotic equilibrium, acid-base balance).

Paediatric population

There is no clinical experience on the use of this product in children. This medicinal product is not recommended for use in children until further data become available (see sections 7 and 9).

4.2 Pharmacokinetic Properties

This medicinal product must only be administered intravenously or used as haemodialysis solution.

Distribution/ Biotransformation/ Elimination

The distribution of electrolytes and bicarbonate is regulated in accordance with requirements and the metabolic status and residual renal function. The active substances of this medicinal product are not metabolised except for glucose. The elimination of water and electrolytes depends on cellular requirements, the metabolic status, the residual renal function, and on other routes of fluid losses (e.g., gut, lung, and skin).

5. Indication

multiBic potassium-free is indicated for intravenous use as substitution solution in haemofiltration and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration.

For use in patients

- with acute kidney injury requiring continuous renal replacement therapy: continuous haemodialysis, haemofiltration or haemodiafiltration treatments.
- with chronic kidney disease in whom a transient treatment is indicated, e.g. during the stay on an intensive care unit.
- when continuous renal replacement therapy is indicated as part of the treatment of an intoxication with water soluble, filterable/dialyzable toxins.

multiBic potassium-free is indicated in adults.

6. Recommended Dose

Continuous renal replacement therapy including the prescription of this medicinal product should be performed under the direction of a physician with experience in these treatments.

7. Mode of Administration

In acute kidney injury, a continuous treatment with a dose of 2000 ml/h multiBic potassium-free is appropriate in adults with a body weight of 70 kg to remove metabolic waste products depending on the metabolic status of the patient. The dose should be adapted to the body size of the patient.

In patients with chronic kidney disease, unless clinically indicated otherwise, the dose of multiBic potassium-free should be at least one third of the body weight per session with three sessions applied per week. Increasing the volume applied per week or distributing this weekly volume to more than 3 treatments per week can be required.

The dose and the duration of haemodialysis, haemofiltration or haemodiafiltration necessary in treatment of acute states of intoxication depends on the toxin and its concentration and the severity of clinical symptoms and has to be clinically decided on the individual patient's condition.

A maximum dose of 75 litre per day is recommended.

Paediatric population

The safety and efficacy of multiBic potassium-free in children have not yet been established (see sections 9 and 4.1).

Method of administration

For intravenous use and haemodialysis.

Do not use unless the ready-to-use solution is clear and colourless and the bag and connectors are undamaged.

For single use only. Any unused solution must be discarded.

Must be used by means of metering pumps.

Instructions for use

The solution for haemodialysis/haemofiltration should be administered in three steps:

1. Removal of the protective foil and careful inspection of the bag

The protective foil should only be removed immediately before administration.

Plastic containers may occasionally be damaged during transport from the manufacturer to the clinic or within the clinic itself. This can lead to contamination and microbiological or fungal growth in the solutions. Therefore, careful visual inspection of the bag and the solutions before mixing is necessary. Particular attention should be paid to even the slightest damage to the closure, the welded seam and the corners of the bag in view of a possible contamination.

2. Mixing of the two compartments

The two-compartment-bag - the bicarbonate and the electrolytes including glucose compartments - are mixed immediately before use to obtain a ready-for-use solution.

A)

Unfold the small compartment.

B)

Roll up the solution bag starting from the corner opposite the small compartment…

C)

… until the peel seam between both compartments has opened along its entire length and the solutions from both compartments are mixed.

After mixing both compartments, it must be checked, that the peel seam is completely open, that the mixed solution is clear and colourless and that the bag is not leaking.

3. Application of the ready-to-use solution

The ready-to-use solution must be used immediately, but within a maximum of 48 hours after mixing.

Any admixture to the ready-to-use solution must only be done after the ready-to-use solution has been thoroughly mixed. After such an admixture, the ready-to-use solution should again be thoroughly mixed prior to use.

Admixtures of sodium chloride solution (concentration between 3 % and 30 % sodium chloride; up to 250 mmol sodium chloride per 5 litre multiBic solution) and water for injection (up to 1250 ml per 5 litre multiBic solution) are compatible with this medicinal product.

If not otherwise prescribed, the ready-to-use solution should be warmed immediately before use to 36.5 °C – 38.0 °C. The exact temperature must be selected depending on clinical requirements and the technical equipment used.

No special requirements for disposal. This medicinal product must not be mixed with other medicinal products except those mentioned above.

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8. Contraindication

Solution related contraindications:

- Hypersensitivity to the active substances or to any of the excipients listed in section 2
- Hypokalaemia
- Metabolic alkalosis

Contraindications for use of the technical procedure itself:

- Inadequate blood flow from vascular access.
- If there is a high risk of haemorrhage on account of systemic anticoagulation.

9. Warnings and Precautions

Use only after mixing of the two solutions.

multiBic potassium-free should be warmed prior to use with appropriate equipment to approximately body temperature and must not be used under any circumstances below room temperature.

The warming of the ready-to-use solution to approximately body temperature must be carefully controlled verifying that the ready-to-use solution is clear and without particles.

During application of the ready-to-use solution, white calcium carbonate precipitation has been observed in the tubing lines in rare cases, particularly close to the pump unit and the heating unit warming the ready-to-use solution.

Precipitations particularly can occur if the temperature of the ready-to-use solution at the inlet of the pump unit is already higher than 30 °C.

Therefore, the ready-to-use solution in the tubing lines must be closely visually inspected every 30 min during continuous renal replacement therapy in order to ensure, that the solution in the tubing system is clear and free from precipitate. Precipitations may occur also with substantial delay after start of treatment.

If precipitate is observed, the ready-to-use solution and the tubing lines used for continuous renal replacement therapy must be replaced immediately and the patient carefully monitored.

The serum potassium concentration must be checked regularly before and during continuous renal replacement therapy. The potassium status of the patient and its trend during the treatment must be considered:

In case of hypokalaemia supplementation of potassium and / or changing to a solution for haemodialysis/ haemofiltration with higher potassium concentration may be required.

In case of hyperkalaemia an increase in the applied dose and / or change to a solution for haemodialysis/ haemofiltration with a lower potassium concentration may be indicated as well as usual measures of intensive care medicine.

The serum sodium concentration must be checked regularly before and during use of this solution for haemodialysis/haemofiltration to control risks related to hypo/hypernatraemia. The solution for haemodialysis/ haemofiltration may be diluted with an adequate amount of water for injections or concentrated sodium chloride solution may be added if required. The speed of desired normalisation must then be carefully planned to avoid adverse reactions due to rapid changes in serum sodium concentration.

In addition, the following parameters must be monitored before and during continuous renal replacement therapy: Serum calcium, serum magnesium, serum phosphate, serum glucose, acid-base status, levels of urea and creatinine, body weight and fluid balance (for the early recognition of hyper- and dehydration).

Clinically important substances may be removed with the haemodialysis, haemofiltration and haemodiafiltration treatment and are not supplemented with this medicinal product. This removal of important nutrients must be compensated by adequate nutrition, nutritional supplements, or an adapted parenteral nutrition.

Paediatric population

There is no clinical experience on the use of this product in children. This medicinal product is not recommended for use in children until further data become available (see sections 7 and 4.1).

10. Interactions With Other Medicaments

No interaction studies have been performed.

The correct dose of multiBic potassium-free and strict monitoring of clinical chemistry parameters and vital signs will avoid risks related to interactions with other medicinal products.

The following interactions are conceivable:

- Toxic effects of digitalis may be masked by hyperkalaemia, hypermagnesaemia and hypocalcaemia. The correction of these electrolytes by continuous renal replacement therapy may precipitate signs and symptoms of digitalis toxicity, e.g. cardiac arrhythmia.
- Electrolyte substitutions, parenteral nutrition and other infusions usually given in intensive care medicine interact with the serum composition and the fluid status of the patient. This must be considered during application of continuous renal replacement therapy.
- Continuous renal replacement therapy may reduce the blood concentration of drugs, especially of drugs with a low protein binding capacity, with a small distribution volume, with a molecular weight below the cut-off of the haemofilter and of medicinal products adsorbed to the haemofilter. An appropriate revision of the dose of such medicinal products may be required.

11. Pregnancy and Lactation

There are no or limited amount of data from the use of multiBic potassium-free in pregnant women. Animal studies are insufficient with respect to reproductive toxicity.

multiBic potassium-free should not be used during pregnancy unless the clinical condition of the woman requires continuous renal replacement therapy.

There is insufficient information on the excretion of multiBic potassium-free active substances/metabolites in human milk.

Breastfeeding is not recommended during treatment with multiBic potassium-free.

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Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

For suspected adverse drug reaction, report to FMCPI.PV@freseniusmedicalcare.com and FDA: www.fda.gov.ph.

13. Overdose and treatment

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Frankfurter Straße 6-8,
66606 St. Wendel, Germany

Imported and Distributed by:

Fresenius Medical Care Philippines Inc.
18/F Aeon Center, corner Alabang-Zapote Road and North Bridgeway, Filinvest Corporate City, Barangay Alabang, Muntinlupa City, Metro Manila.
Caution: Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.
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17. Date of Revision of Package Insert

The insert was last revised in June 2021

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