0/12620111/0321

⚠ **Information for use – Please read carefully!** CE 0123 GB

Haemodialysis Liquid Concentrate NKFS-0x (Acid)

Composition of the ready-to-use bicarbonate haemodialysis solution

Sodium Bicarbonate 8.4% (bicarbonate concentrate) + water + NKFS-0x (acid concentrate) yield a ready-to-use bicarbonate haemodialysis solution.

For the electrolyte concentration and theoretical osmolarity of this ready-to-use solution, please refer to the product label of the acid concentrate used.

Water for the dilution of haemodialysis concentrates has to comply with European Pharmacopoeia monograph 1167 requirements.

Note: Drinking water is not suitable for the preparation of bicarbonate haemodialysis solutions.

Indications

The indications below apply exclusively to the ready-to-use bicarbonate haemodialysis solution prepared from acid concentrate and bicarbonate concentrate following the specified dilution procedure:

- Acute renal failure
- Chronic renal failure
- Hyperhydration
- Intoxications
- Compensation of acid-base and electrolyte balances
- Adjustment of the blood / plasma / body temperature

Contraindications

- Hyperkalaemia with the use of a potassium-containing acidic bicarbonate haemodialysis concentrate
- Hypokalaemia with the use of a potassium-free acidic bicarbonate haemodialysis concentrate
- Intractable coagulopathy

  In patients with unstable circulation and/or unstable blood pressure, a different extracorporeal method of treatment may be indicated.

Usage in Pregnancy

Safety of NKFS-0x (acid concentrate) for haemodialysis treatment has not been determined in pregnant women.

The products should be used only when clearly needed as prescribed by the physician.

Adverse Reactions

During haemodialysis, hypotension, nausea, vomiting and muscle cramps may occur.

Dosage

Unless otherwise directed, mix 1.000 l NKFS-0x (acid concentrate) and 1.225 l Sodium Bicarbonate 8.4% with 32.775 l water of suitable quality. Please refer to the product label of the acid concentrate used for details of the mixing ratio.

Mode and duration of administration

For extracorporeal bicarbonate haemodialysis or bicarbonate haemodiafiltration.

The duration of administration must be determined on an individual basis.

Warnings and precautions

NKFS-0x (acid concentrate) may only be used in combination with Sodium Bicarbonate 8.4% following a specified dilution procedure.
The ready-to-use bicarbonate haemodialysis solution must be tested before use by a suitable gas analysis method.

For safe use refer to equipment manufacturer's instructions.

Acid concentrate and bicarbonate concentrate should be diluted only immediately before use.

Discard unused portions.

The concentration of the ready-to-use bicarbonate haemodialysis solution must be carefully monitored.

Use only if solution is clear and colourless.

Do not use after expiry date.

Do not use damaged containers.

Concentrates are endotoxin free.

Presentation

5 l and 10 l plastic container.

Storage Condition

The product should not be stored above the temperature stated on the label.

KEEP OUT OF REACH OF CHILDREN

Rev. date : 03 / 2021

Manufacturing date

Expiry date

LOT Batch no.

B BRAUN

Manufacturing facility:
B. Braun Medical Industries Sdn. Bhd.
Bayan Lepas Free Industrial Zone
11900 Penang, Malaysia

B. Braun Avitum AG
34209 Melsungen, Germany

Approval for Printing
B BRAUN Melsungen AG

Approved for Printing ☐

Approved for Printing when corrected ☐

New draft required ☐

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LMS: _____ Date Signature

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Haemodialysis Concentrate
NKFS-0x (Acid)
0/12620111/0321
Production site: Penang

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4005

Font size: 7 pt.

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⚠ **Information for use – Please read carefully!** CE 0123 SG

Haemodialysis Liquid Concentrate NKFS-0x (Acid)

x = 1/2/3/4

Not all formulas is available locally.

Composition of the ready-to-use bicarbonate haemodialysis solution

Sodium Bicarbonate 8.4% (bicarbonate concentrate) + water + NKFS-0x (acid concentrate) yield a ready-to-use bicarbonate haemodialysis solution.

For the electrolyte concentration and theoretical osmolarity of this ready-to-use solution, please refer to the product label of the acid concentrate used.

Water for the dilution of haemodialysis concentrates has to comply with European Pharmacopoeia monograph 1167 requirements.

Note: Drinking water is not suitable for the preparation of bicarbonate haemodialysis solutions.

Indications

The indications below apply exclusively to the ready-to-use bicarbonate haemodialysis solution prepared from acid concentrate and bicarbonate concentrate following the specified dilution procedure:

- Acute renal failure
- Chronic renal failure
- Hyperhydration
- Intoxications
- Compensation of acid-base and electrolyte balances
- Adjustment of the blood / plasma / body temperature

Contraindications

- Hyperkalaemia with the use of a potassium-containing acidic bicarbonate haemodialysis concentrate
- Hypokalaemia with the use of a potassium-free acidic bicarbonate haemodialysis concentrate
- Intractable coagulopathy

  In patients with unstable circulation and/or unstable blood pressure, a different extracorporeal method of treatment may be indicated.

Usage in Pregnancy

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Mode and duration of administration

For extracorporeal bicarbonate haemodialysis or bicarbonate haemodiafiltration.

The duration of administration must be determined on an individual basis.

Warnings and precautions

NKFS-0x (acid concentrate) may only be used in combination with Sodium Bicarbonate 8.4% following a specified dilution procedure.

The ready-to-use bicarbonate haemodialysis solution must be tested before use by a suitable gas analysis method.

For safe use refer to equipment manufacturer's instructions.

Acid concentrate and bicarbonate concentrate should be diluted only immediately before use.

Discard unused portions.

The concentration of the ready-to-use bicarbonate haemodialysis solution must be carefully monitored.

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