

**AQUACID-120- acid concentrate for hemodialysis solution, concentrate  
Aqua Medica, S.A. de C.V.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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This is a Hemodialysis Acid Concentrate, Pyrogen-Free.

By diluting one part of this acid concentrate with 44 parts of purified water (ISO Standard 13959:2014), each 1000 ml of this solution provides:

Sodium: 130.00 mEq/l

Potassium: 2.00 mEq/l

Calcium: 2.50 mEq/l

Magnesium: 1.00 mEq/l

Chlorides: 108.50 mEq/l

Acetate: 3.00 mEq/l

Dextrose: 100.00 mEq/l

The final conductivity calculated at 25 C is 13.2 to 14.2 mS/cm.

**Active Ingredient(s)**

Potassium Chloride

**Purpose**

For use with 3-pump hemodialysis machines only.

**Use**

For use with 3-pump hemodialysis machines only, using purified water (Standard 13959:2014) and in combination with sodium bicarbonate.

**Warnings**

For use with 3-pump hemodialysis machines only.

**Do not use**

- If the warranty seal is damaged or broken and do not allow debris to fall into the concentrate.

Using purified water (Standard 13959:2014) and in combination with sodium bicarbonate.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

If you do not use the entire contents, discard the excess.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- By diluting one part of this acid concentrate with 44 parts of purified water (ISO Standard 13959:2014).

**Inactive ingredients**


Sodium chloride, calcium chloride, acetic acid, dextrose, purified water USP

**Other information**

- Store at room temperature.

**Package Label - Principal Display Panel**

**3,785 liters**  
( 1 gallon )



# AQUACID®-120

**ACID CONCENTRATE FOR HEMODIALYSIS**

PYROGEN-FREE

By diluting one part of acid concentrate with 34 parts of purified water ( standard UNE-EN ISO 23500-3:2019 )  
Each 1000 ml of this solution provides:

|                |              |
|----------------|--------------|
| Sodium.....    | 103,00 mEq/l |
| Potassium..... | 2,00 mEq/l   |
| Calcium.....   | 2,50 mEq/l   |
| Magnesium..... | 1,00 mEq/l   |
| Chlorides..... | 108,50 mEq/l |
| Acetate.....   | 3,00 mEq/l   |
| Dextrose.....  | 100,00 mg/dl |

The final conductivity calculated at 25°C is 13.2 to 14.2 mS/cm.

|                         |          |
|-------------------------|----------|
| Sodium chloride.....    | 210,70 g |
| Potassium chloride..... | 5,22 g   |
| Calcium chloride.....   | 4,86 g   |
| Magnesium chloride..... | 1,67 g   |
| Acetic acid.....        | 6,31 g   |
| Dextrose.....           | 35,00 g  |

**2-K**

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**WARNING:**

For use with 3-pump hemodialysis machines only, using purified water ( standard UNE-EN ISO 23500-3:2019 ) and in combination with sodium bicarbonate. Shake before using. Check the dilution of the Sodium bicarbonate. Do not use if the warranty seal is damaged or broken and do not allow debris to fall into the concentrate. Keep container tightly closed when not in use.

**If you do not use the entire contents, discard the excess. Store at room temperature.**

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Made in México:  
**AQUA Medica, S.A. de C.V.**  
Carr. Fed. Méx-Cuautla km 65.8 No. 8  
Col. Tetelcingo, 62757 Cuautla, Mor.

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REG. No. : **01988C99 SSA**

AQUA Medica, S.A. de C.V. IS NOT RESPONSIBLE FOR THE INCORRECT DISPOSAL OF THIS CONTAINER. DISPOSE OF LEFT OVER PRODUCT ACCORDING TO THE SAFETY DATA SHEET..

REV 06

3785 mL NDC: 81943-604-02

## AQUACID-120

acid concentrate for hemodialysis solution, concentrate

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:81943-604 |
| <b>Route of Administration</b> | HEMODIALYSIS   |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength  | Strength             |
|---|--------------------|----------------------|
| <b>POTASSIUM CHLORATE</b> (UNII: H35KS68EE7) (CHLORATE ION - UNII:08Z8093742) | POTASSIUM CHLORATE | 0.671 g<br>in 100 mL |

### Inactive Ingredients

| Ingredient Name                              | Strength          |
|--|-------------------|
| <b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O) | 0.167 g in 100 mL |

|  |                   |
|--|-------------------|
| <b>CALCIUM CHLORIDE</b> (UNII: M4I0D6VV5M) | 0.486 g in 100 mL |
| <b>ACETIC ACID C-11</b> (UNII: 2A9OM7IPNW) | 0.361 g in 100 mL |
| <b>DEXTROSE</b> (UNII: IY9XDZ35W2)         | 3.5 g in 100 mL   |
| <b>WATER</b> (UNII: 059QF0KO0R)            |                   |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)  | 21.07 g in 100 mL |

### Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:81943-604-02 | 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020           |                    |

### Marketing Information

| Marketing Category       | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug<br>other |  | 03/30/2020           |                    |

**Labeler** - Aqua Medica, S.A. de C.V. (589696442)

### Establishment

| Name                      | Address | ID/FEI    | Business Operations    |
|---------------------------|---------|-----------|------------------------|
| Aqua Medica, S.A. de C.V. |         | 589696442 | manufacture(81943-604) |

Revised: 11/2024

Aqua Medica, S.A. de C.V.