**AQUACID-220- 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 diluiting one part of this acid concentrate with 34 parts of purified water (ISO Standard 13959:2014), each 1000 ml of this solucion provides:

Sodium: 103.00 mEq/l

Potassium: 0.00 mEq/l

Calcium: 2.50 mEq/l

Magnesium: 1.00 mEq/l

Chlorides: 106.50 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 34 parts of purified water (ISO Standard 13959:2014).

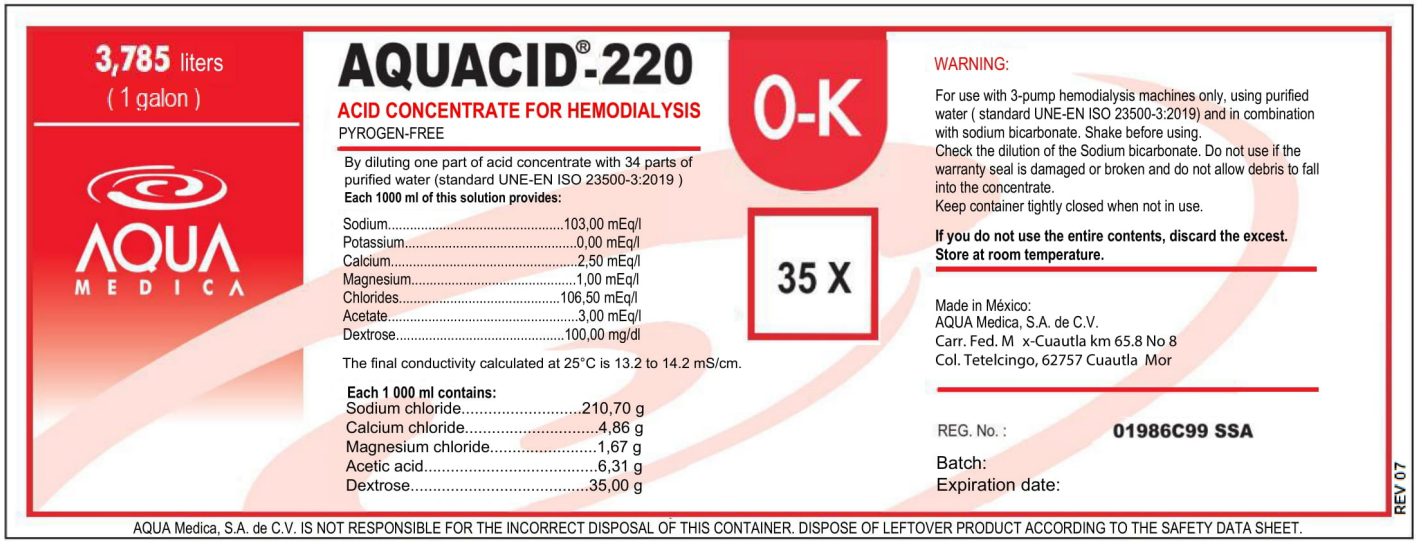
**Other information**

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

**Inactive ingredients**

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

**Package Label - Principal Display Panel**




3785 mL NDC: 81943-602-04

# AQUACID-220

acid concentrate for hemodialysis solution, concentrate

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:81943-602 |
| **Route of Administration** | HEMODIALYSIS | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **POTASSIUM CHLORATE** (UNII: H35KS68EE7) (CHLORATE ION - UNII:08Z8093742) | POTASSIUM CHLORATE | 0.671 g in 100 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | 21.07 g in 100 mL |

| | |
|---|---|
| **MAGNESIUM CHLORIDE** (UNII: 02F3473H9O) | 0.167 g in 100 mL |
| **CALCIUM CHLORIDE** (UNII: M4I0D6VV5M) | 0.486 g in 100 mL |
| **ACETIC ACID C-11** (UNII: 2A9OM7IPNW) | 0.631 g in 100 mL |
| **DEXTROSE** (UNII: IY9XDZ35W2) | 3.5 g in 100 mL |
| **WATER** (UNII: 059QF0KO0R) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:81943-602-04 | 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 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(81943-602) |

Revised: 11/2024 Aqua Medica, S.A. de C.V.