# AQUACID-100- 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 44 parts of purified water (ISO Standard 13959:2014), each 1000 ml of this solucion provides:

Sodium: 100.00 mEq/l

Potassium: 2.00 mEq/l

Calcium: 3.00 mEq/l

Magnesium: 0.75 mEq/l

Chlorides: 105.75 mEq/l

Acetate: 4.00 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).

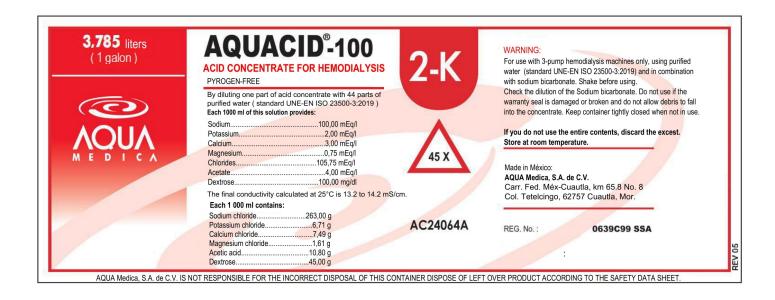
#### Other information

• Store at room temperature.

## **Inactive ingredients**

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

# **Package Label - Principal Display Panel**



3785 mL NDC: 81943-605-01

# **AQUACID-100**

acid concentrate for hemodialysis solution, concentrate

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:81943-605 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		
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	0.161 g in 100 mL		

ACETIC ACID C-11 (UNII: 2A9OM7IPNW)	1.08 g in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	0.749 g in 100 mL
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	24.3 g in 100 mL
DEXTROSE (UNII: IY9XDZ35W2)	4.5 g in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:81943- 605-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information			
eting End Date	Monograph Marketing Start Date	Application Number or Monograph Citation	Marketing Category
	03/30/2020		unapproved drug other
	03/30/2020		unapproved drug other

# **Labeler -** AQUA MEDICA, S.A. DE C.V. (816672224)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
AQUA MEDICA, S.A. DE C.V.		816672224	manufacture(81943-605)	

Revised: 10/2023 AQUA MEDICA, S.A. DE C.V.