# 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.

-----

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: 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).

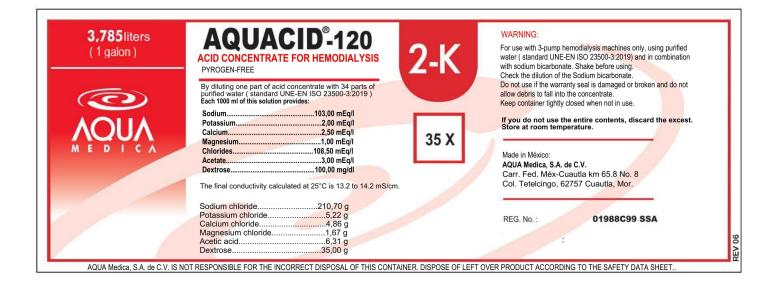
## Inactive ingredients

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

## Other information

• Store at room temperature.

## Package Label - Principal Display Panel



#### 3785 mL NDC: 81943-604-02

AQUACID-120						
acid concentrate for hemodia	alysis solution, concent	rate				
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:		NDC:81943-604		
Route of Administration	HEMODIALYSIS					
Active Ingredient/Active Moiety						
Ingre	dient Name		Basis of Strength	Strength		
POTASSIUM CHLORATE (UNII: H UNII:08Z 8093742)	35KS68EE7) (CHLORATE ION	-	POTAS SIUM CHLORATE	0.671 g in 100 mL		
Inactive Ingredients						
Ing	redient Name			Strength		
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)			0.167 g in 100 mL			

# Item Code	Package Description	Marketing Start Date	Marketing End		
Packaging					
SODIUM CHLORIDE	01011: 45170471Q8X)	21.07 g in	100 ML		
		21.07 a in	100 ml		
WATER (UNII: 059QF0KO0R)					
DEXTROSE (UNII: IY9)	(DZ 35W2)	3.5 g in 100 mL			
ACETIC ACID C-11 (	JNII: 2A9OM7IPNW)	0.361 g in 100 mL			
CALCIUM CHLORIDE	(UNII: M4I0D6VV5M)	0.486 g in 100 mL			

		r dekuge beschption	Date	Date	
1	NDC:81943- 604-02	85 mL in 1 BOTTLE; Type 0: Not a Combination 03/30/2020			
Marketing Information					
Μ	larketing	Information			
Μ	larketing Marketing Category	Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	

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

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

Revised: 11/2024

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