AQUACID-200- 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: 100.00 mEq/l

Potassium: 0.00 mEq/l

Calcium: 3.00 mEq/l

Magnesium: 0.75 mEq/l

Chlorides: 103.75 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).

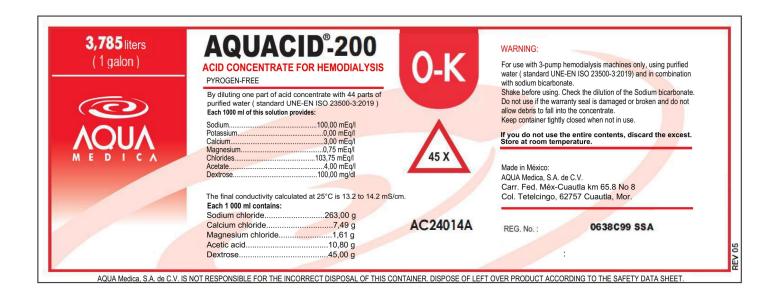
Other information

- Store at room temperature.
- Keep container tightly closed when not in use.

Inactive ingredients

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

Package Label - Principal Display Panel



3785 mL NDC: 81943-603-03

AQUACID-200

acid concentrate for hemodialysis solution, concentrate

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81943-603
Route of Administration	HEMODIALYSIS		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
	POTASSIUM CHLORATE	0.671 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
SODIUM CHLORIDE (UNII: 451W47IQ8X)	26.3 g in 100 mL		

ACETIC ACID C-11 (UNII: 2A9OM7IPNW)	1.08 g in 100 mL
DEXTROSE (UNII: IY9XDZ 35W2)	4.5 g in 100 mL
WATER (UNII: 059QF0KO0R)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	0.161 g in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	0.749 g in 100 mL

ı	Packaging			
# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1 NDC:81943- 603-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

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

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

Establishment				
Name	Address	ID/FEI	Business Operations	
AQUA MEDICA, S.A. DE C.V.		816672224	manufacture(81943-603)	

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