

**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 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: 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

3,785 liters
(1 gallon)



AQUACID[®]-200
ACID CONCENTRATE FOR HEMODIALYSIS
PYROGEN-FREE

By diluting one part of acid concentrate with 44 parts of purified water (standard UNE-EN ISO 23500-3:2019)
Each 1000 ml of this solution 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 mg/dl

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

Each 1 000 ml contains:

Sodium chloride.....	263,00 g
Calcium chloride.....	7,49 g
Magnesium chloride.....	1,61 g
Acetic acid.....	10,80 g
Dextrose.....	45,00 g

O-K

45 X

AC24014A

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.

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

REG. No. : **0638C99 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 05

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 (UNII: H35KS68EE7) (CHLORATE ION - UNII:08Z8093742)	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
DEXTRROSE (UNII: IY9XDZ35W2)	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

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 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. (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.