AQUACETIC-30- cleaning solution for hemodialysis machines solution, concentrate AQUA MEDICA, S.A. DE C.V.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

INDUSTRIAL VINEGAR FOR THE CLEANING OF HEMODIALYSIS MACHINES

Glacial Acetic Acid

This product is used to descale and clean hemodialysis machines.

For use with 3-pump hemodialysis machines only, using purified water.

Avoid contact with skin and eyes.

Do not mix with hypochlorite, or with hydrogen peroxide, or in general with any chemical base.

Do not mix with hypochlorite, or with hydrogen peroxide, or in general with any chemical base.

Take appropriate security measures (protective clothing, glasses, masks).

If you do not use the entire contents, discard the excess.

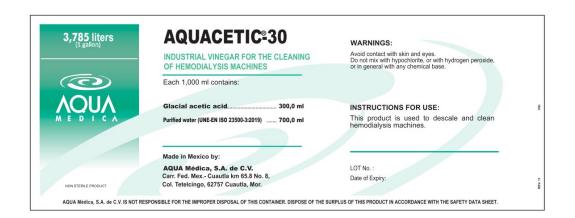
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

This product is used to descale and clean hemodialysis machines.

Store at room temperature.

Keep container tightly closed when not in use.

Water.



81943-801-01

AQUACETIC-30

cleaning solution for hemodialysis machines solution, concentrate

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81943-801
Route of Administration	HEMODIALYSIS		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.3 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)	0.7 g in 100 mL		

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:81943- 801-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2023	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	03/30/2023		

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(81943-801)	

Revised: 8/2023 AQUA MEDICA, S.A. DE C.V.