

**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.*

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**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.

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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.

**3,785 liters**  
(1 gallon)



NON STERILE PRODUCT

## AQUACETIC®-30

**INDUSTRIAL VINEGAR FOR THE CLEANING OF HEMODIALYSIS MACHINES**

Each 1,000 ml contains:

**Glacial acetic acid** ..... 300,0 ml

**Purified water (UNE-EN ISO 23500-3:2019)** ..... 700,0 ml

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**Made in Mexico by:**  
**AQUA Médica, S.A. de C.V.**  
Carr. Fed. Mex. - Cuautla km 65,8 No. 8,  
Col. Tetelcingo, 62757 Cuautla, Mor.

**WARNINGS:**  
Avoid contact with skin and eyes.  
Do not mix with hypochlorite, or with hydrogen peroxide,  
or in general with any chemical base.

**INSTRUCTIONS FOR USE:**  
This product is used to descale and clean hemodialysis machines.

LOT No. :  
Date of Expiry:

AQUA Médica, S.A. de C.V. IS NOT RESPONSIBLE FOR THE IMPROPER DISPOSAL OF THIS CONTAINER. DISPOSE OF THE SURPLUS OF THIS PRODUCT IN ACCORDANCE WITH THE SAFETY DATA SHEET.

81943-801-01

<b>AQUACETIC-30</b>			
cleaning solution for hemodialysis machines solution, concentrate			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81943-801
<b>Route of Administration</b>	HEMODIALYSIS		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.3 g in 100 mL	
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>	<b>Strength</b>		
<b>WATER</b> (UNII: 059QF0KO0R)	0.7 g in 100 mL		

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	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.