

# **CITRACID-50- desinfectant solution for hemodialysis machine 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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This product is used to descale and disinfect Hemodialysis machines.

Citric Acid

For use with 3-pump hemodialysis machines only.

For use with 3-pump hemodialysis machines only, using purified water (Standard UNE-EN ISO 23500-3:2019).

Avoid contact with skin and eyes.

Irritation hazard if spilled or splashed.

If the warranty seal is damaged or broken and do not allow debris to fall into the concentrate.

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

Wash splashes on skin or clothing with plenty of water.

If 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.

By diluting one part of this acid concentrate with one part of purified water.

Store at room temperature.

Keep container tightly closed when not in use.

Water.

**5,0 liters**

**CITRACID<sup>®</sup>-50**

Each 1,000 g contains:

**Citric acid.....500,0 g**  
**Purified water (standard UNE-EN ISO 23500-3:2019) ..500,0 g**

**INSTRUCTIONS FOR USE:**  
This product is used to descale and disinfect Hemodialysis machines.

**WARNINGS:**  
Avoid contact with skin and eyes  
Irritation hazard if spilled or splashed.

\* Take appropriate security measures (protective clothing, glasses, masks).  
\* Wash splashes on skin or clothing with plenty of water.

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.

**LOT No.:**  
**Date of Expiry:**

NON STERILE PRODUCT

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.

REV. 13

# CITRACID-50

desinfectant solution for hemodialysis machine solution, concentrate

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81943-701
<b>Route of Administration</b>	HEMODIALYSIS		

## Active Ingredient/Active Moiety

<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	0.5 g in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	0.5 g in 100 mL

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:81943-701-01	5000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2023	

## Marketing Information

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

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

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
AQUA MEDICA, S.A. DE C.V.		816672224	manufacture(81943-701)

Revised: 8/2023

AQUA MEDICA, S.A. DE C.V.