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.

This product is used to descale and desinfect Hemodialysis machines.

Citric Acid

For use with 3-pump hemodialysis machines only.

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Avoid contact with skin an 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.

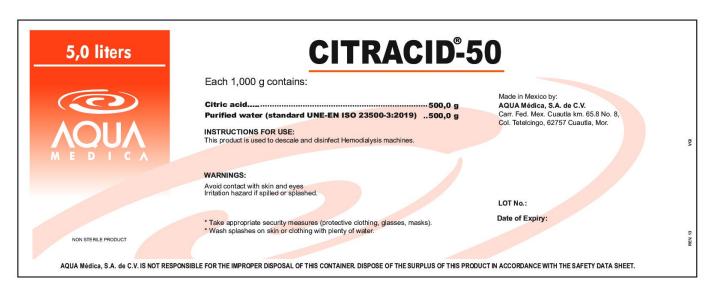
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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.



CITRACID-50

desinfectant solution for hemodialysis machine solution, concentrate

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

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.5 g in 100 mL		

Inactive Ingredients

Ingredient Name	Strength

WATER (UNII: 059QF0KO0R) 0.5 g in 100 mL

Packaging

	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l		NDC:81943- 701-01	5000 mL in 1 CONTAINER; 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(81943-701)	

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