

## **QUABIC-300- hemodialysis grade sodium bicarbonate solution 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.*

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This is a Hemodialysis-Grade Sodium Bicarbonate Solution.

This solution already diluted 1:27:57 with purified water (standard 13959:2014), provides:

Sodium: 35.0 mEq/l

Bicarbonate: 35.0 mEq/l

Each 1000 mL of this solution contains:

Sodium bicarbonate USP, hemodialysis grade: 84.0 g

Purified water (standard ISO 13959:2014), csp: 1000 mL

### **Active Ingredient(s)**

Sodium Bicarbonate: Antiseptic

### **Purpose**

For use only with 3-pump hemodialysis machines.

### **Use**

Use only with 3-pump hemodialysis machines, together with acid concentrate for hemodialysis, diluting with purified water (standard ISO 13959:2014) IN A RATIO 1:1.23:32.77.

### **Warnings**

The solution should be transparent and colorless. Do not use if cloudy or with broken seal. If not all of the contents are used, discard the excess. Keep at room temperature.

For use only with 3-pump hemodialysis machines, together with acid concentrate for hemodialysis, diluting with purified water.

### **Do not use**

- If cloudy or with broken seal.

If not all of the contents are used, discard the excess.

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

### Other information

- Keep at room temperature.

### Inactive ingredients

Purified water (standard ISO 13959:2014)

### Package Label - Principal Display Panel

3785 mL NDC: 81943-502-01

**3,785**  
(1 GALON)

**AQUA MEDICA**

**QUABIC<sup>®</sup>-300**  
HEMODIALYSIS-GRADE SODIUM BICARBONATE SOLUTION

This solution already diluted 1:27:57 with purified water (standard ISO 13959:2014), provides:

Sodium.....35.0 mEq/l  
Bicarbonate.....35.0 mEq/l

Each 1 000 ml of this solution contains:

Sodium bicarbonate USP, hemodialysis grade ..... 84,0 g  
Purified water (standard ISO 13959:2014), csp.....1 000 ml

Made in Mexico:  
AQUA Medica, S.A. de C.V.  
Carr. Fed. Méx-Cuautla km 65,8 No 8  
Col. Tetelcingo, 62757 Cuautla Morelos

**USE INSTRUCTIONS**

Use only with 3-pump hemodialysis machines, together with acid concentrate for hemodialysis, diluting with purified water (standard ISO 13959:2014) in a ratio 1:1.23:32.77.

**WARNING**

THE SOLUTION SHOULD BE TRANSPARENT AND COLORLESS. DO NOT USE IF CLOUDY OR WITH BROKEN SEAL. IF NOT ALL OF THE CONTENTS ARE USED, DISCARD THE EXCESS. KEEP AT ROOM TEMPERATURE.

REG. No. : 1710C2014 SSA  
Batch:  
Expiration date

NON-STERILE PRODUCT (<0.5 EU/ml)

AQUA Medica, S.A. de C.V. is not responsible for the incorrect disposal of this container. Dispose of leftover product according to the safety data sheet.

## QUABIC-300

hemodialysis grade sodium bicarbonate solution solution, concentrate

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81943-502
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<b>Route of Administration</b>	HEMODIALYSIS
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	8.4 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81943-502-01	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(81943-502)

Revised: 10/2023

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