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.

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 oly 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

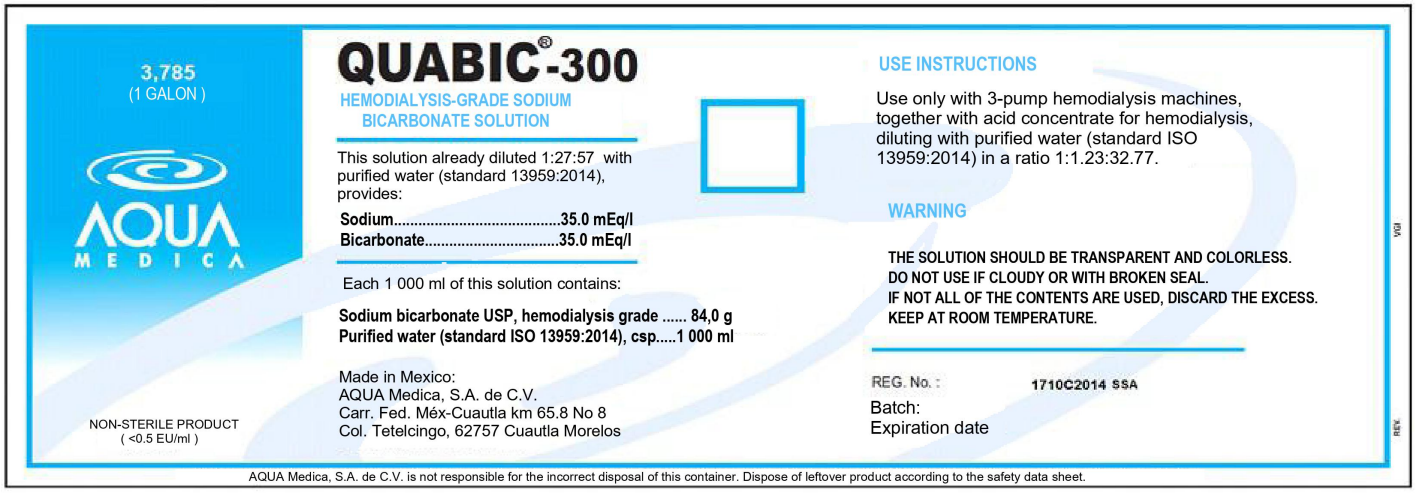
- Keep at room temperature.

Inactive ingredients

Purified water (standard ISO 13959:2014)

Package Label - Principal Display Panel

3785 mL NDC: 81943-502-01



QUABIC-300

hemodialysis grade sodium bicarbonate solution solution, concentrate

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81943-502

Route of Administration	HEMODIALYSIS

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (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. (589696442)

Establishment

Name	Address	ID/FEI	Business Operations
Aqua Medica, S.A. de C.V.		589696442	manufacture(81943-502)

Revised: 11/2025 Aqua Medica, S.A. de C.V.