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

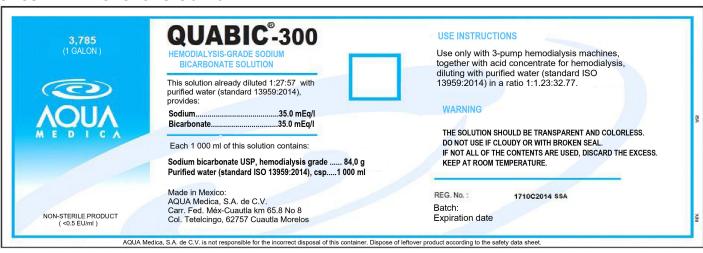
Keep at room temperature.

Inactive ingredients

Purified water (standard ISO 13959:2014)

Package Label - Principal Display Panel

3785 mL NDC: 81943-502-01



Product Type HUMAN OTC DRUG hemodialysis grade sodium bicarbonate solution solution, concentrate Product Information NDC:81943-502

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Active	Ingred	lient/#	ctive	Moiety
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ı	Active ingredient/Active Plotety					
	Ingredient Name	Basis of Strength	Strength			
	SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII: HN1Z RA3Q20)	SODIUM BICARBONATE	8.4 g in 100 mL			

Inactive Ingredients

Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)

Packaging

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	#	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	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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.