QUABIC-100- 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 Solutio.

This solution already diluted 1.27:57 with purified wather (standard 13959:2014), provides:

Sodium: 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

Sodium Bicarbonate: Antiseptic

For use only with 3-pump hemodialysis machines.

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

This 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.

If cloudy or with broken seal.

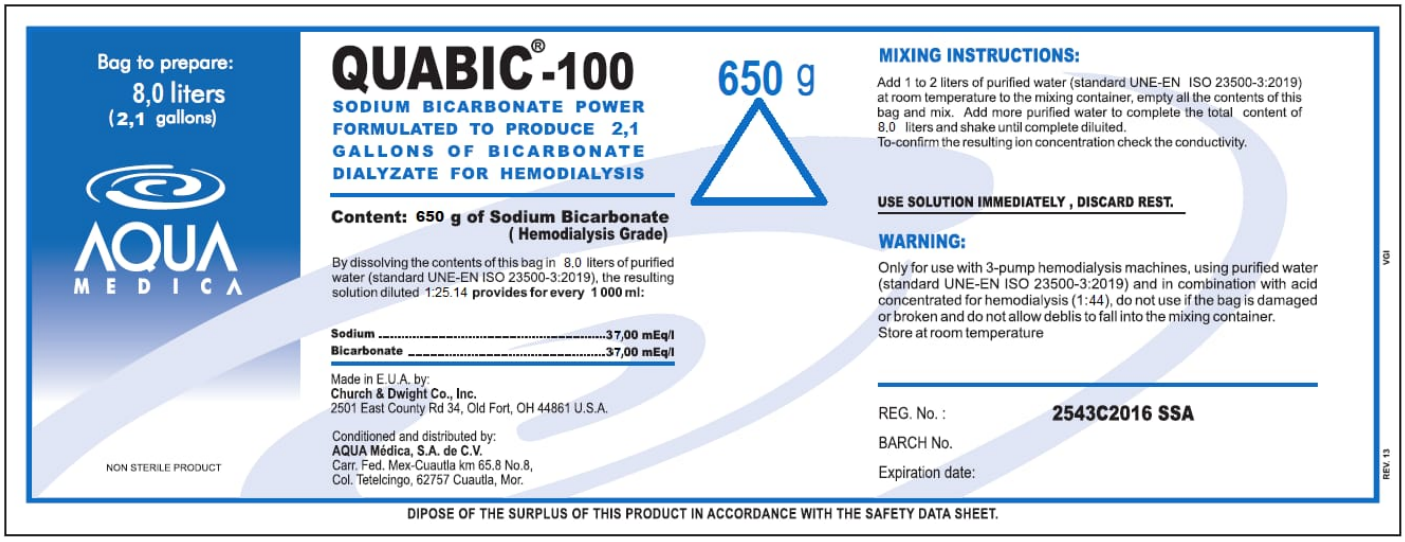
If not all the contents are used, discard the excess.

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

Keep at room temperature.

Purified water (standard ISO 13959:2014)

NDC: 81943-503-02



QUABIC-100

hemodialysis grade sodium bicarbonate solution solution, concentrate

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81943-503
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:81943-503-02	650 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(81943-503)

Revised: 3/2024 Aqua Medica, S.A. de C.V.