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 Hemodialyhsis-Grade Sodium Bicarbonate Solution.

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

Sodium: 35.0 mEq/L

Each 1000 mL of this solution conteins:

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 borken seal.

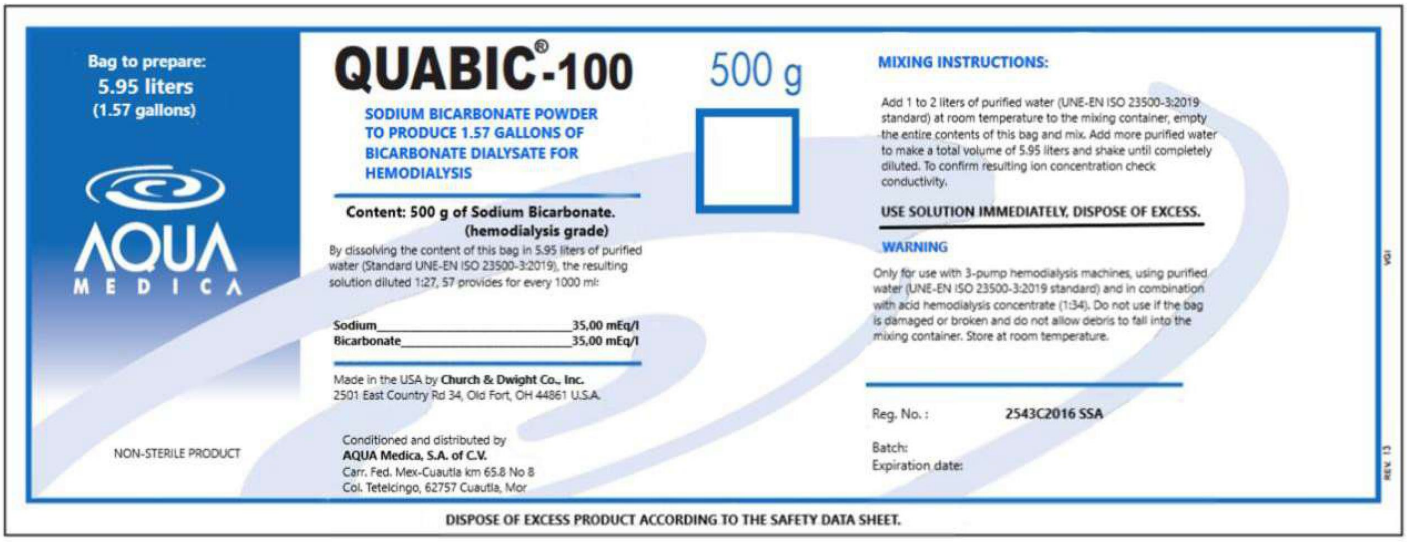
If not all the contents are used, discard the excess.

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)

81943-503-03


Bag to prepare:
5.95 liters
(1.57 gallons)
AQUA MEDICA
QUABIC®-100
500 g
SODIUM BICARBONATE POWDER TO PRODUCE 1.57 GALLONS OF BICARBONATE DIALYSATE FOR HEMODIALYSIS
Content: 500 g of Sodium Bicarbonate. (hemodialysis grade)
By dissolving the content of this bag in 5.95 liters of purified water (Standard UNE-EN ISO 23500-3:2019), the resulting solution diluted 1:27, 57 provides for every 1000 ml:
Sodium 35,00 mEq/l
Bicarbonate 35,00 mEq/l
Made in the USA by Church & Dwight Co., Inc.
2501 East Country Rd 34, Old Fort, OH 44861 U.S.A.
NON-STERILE PRODUCT
Conditioned and distributed by
AQUA Medica, S.A. of C.V.
Carr. Fed. Mex-Cuautla km 65.8 No 8
Col. Tetelcingo, 62757 Cuautla, Mor
MIXING INSTRUCTIONS:
Add 1 to 2 liters of purified water (UNE-EN ISO 23500-3:2019 standard) at room temperature to the mixing container, empty the entire contents of this bag and mix. Add more purified water to make a total volume of 5.95 liters and shake until completely diluted. To confirm resulting ion concentration check conductivity.
USE SOLUTION IMMEDIATELY, DISPOSE OF EXCESS.
WARNING
Only for use with 3-pump hemodialysis machines, using purified water (UNE-EN ISO 23500-3:2019 standard) and in combination with acid hemodialysis concentrate (1:34). Do not use if the bag is damaged or broken and do not allow debris to fall into the mixing container. Store at room temperature.
Reg. No.: 2543C2016 SSA
Batch:
Expiration date:
DISPOSE OF EXCESS PRODUCT ACCORDING TO THE SAFETY DATA SHEET.

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:81943-503-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/30/2024	

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: 11/2024 Aqua Medica, S.A. de C.V.