

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 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 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 (standard 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)

Bag to prepare:
5,95 liters
(1,57 gallons)



**AQUA
MEDICA**

NON STERILE PRODUCT

QUABIC[®]-100

500 g

**SODIUM BICARBONATE POWDER
FORMULATED TO PRODUCE 1.57
GALLONS OF BICARBONATE
DIALYZATE FOR HEMODIALYSIS**

**Content: 500 g of Sodium Bicarbonate
(Hemodialysis degree)**

By dissolving the contents 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 1 000 ml:

Sodium.....35,0 mEq/l
Bicarbonate.....35,0 mEq/l

Made in the E.U.A. by:
Church & Dwight Co., Inc.
2501 East County Rd 34, Old Fort, OH 44861 U.S.A.

Conditioned and distributed by:
AQUA Medica, S.A. de C.V.
Carr. Fed. Méx-Cuautla km 65.8 No 8
Col. Teteicingo, 62757 Cuautla, Mor.

MIXING INSTRUCTIONS:
Add 1 to 2 liters of purified water (standard UNE-EN ISO 23500-3: 2019) at room temperature to the mixing container, empty all the contents of this bag and mix. Add more purified water to complete the total content of 5,95 liters and shake until complete diluted.
To confirm the resulting ion concentration check the conductivity.

USE SOLUTION IMMEDIATELY, DISCARD EXCESS.

WARNING
Only for use with 3-pump hemodialysis machines, using purified water (standard UNE-EN ISO 23500-3:2019) and in combination with acid concentrated for hemodialysis (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 No.

Date of Expiry:

DISPOSE OF THE SURPLUS OF THIS PRODUCT IN ACCORDANCE WITH THE SAFETY DATA SHEET.

REV 13

3785 mL NDC: 81943-503-01

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:81943-503-01	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(81943-503)

Revised: 10/2023

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