**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.*

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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.

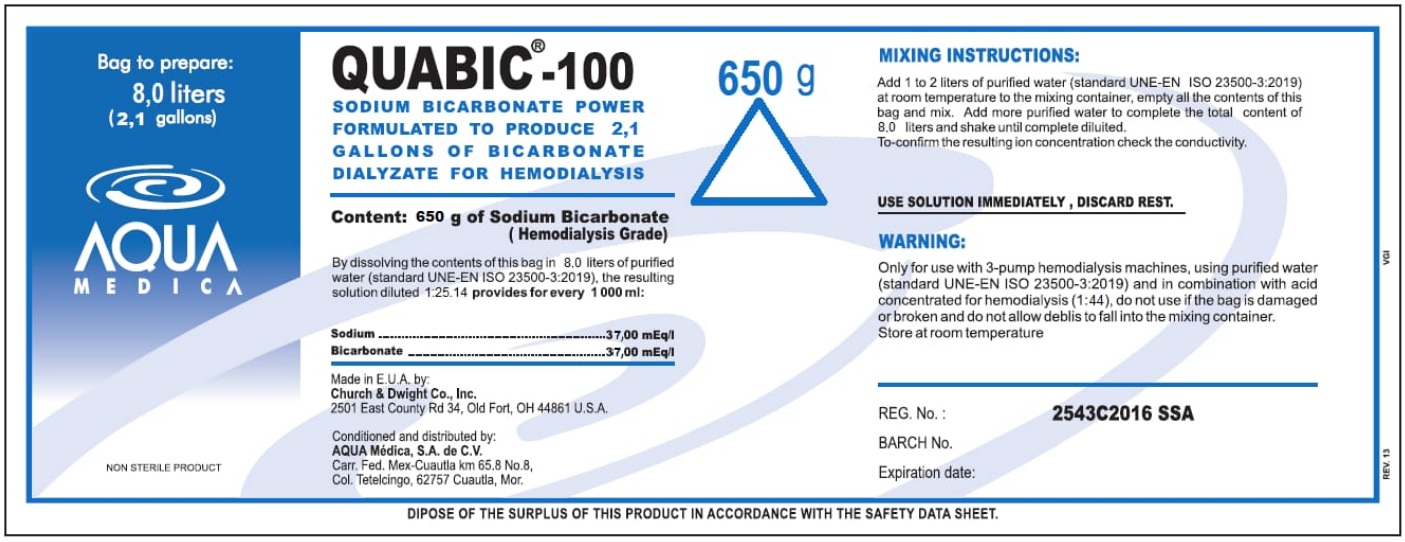
If not all the contents are used, discard the excess.

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