

BALANCED SALT- sodium chloride, potassium chloride, calcium chloride, magnesium chloride, sodium acetate, and sodium citrate solution
B. Braun Medical Inc.

Balanced Salt Solution
Sterile Irrigating Solution

DESCRIPTION

Balanced Salt Solution Sterile Irrigating Solution is a sterile balanced salt solution, each mL containing sodium chloride (NaCl) 0.64%, potassium chloride (KCl) 0.075%, calcium chloride dihydrate ($\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$) 0.048%, magnesium chloride hexahydrate ($\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$) 0.03%, sodium acetate trihydrate ($\text{C}_2\text{H}_3\text{NaO}_2 \cdot 3\text{H}_2\text{O}$) 0.39%, sodium citrate dihydrate ($\text{C}_6\text{H}_5\text{Na}_3\text{O}_7 \cdot 2\text{H}_2\text{O}$) 0.17%, sodium hydroxide and/or hydrochloric acid (to adjust pH), and water for injection.

The pH is approximately 7.0.

The osmolality is approximately 300 mOsm/Kg.

CLINICAL PHARMACOLOGY

Balanced Salt Solution Sterile Irrigating Solution is an isotonic solution for use in irrigating tissues of the eyes.

INDICATIONS AND USAGE

For use as an extraocular and intraocular irrigating solution during ocular surgical procedure involving perfusion of the eye with an expected maximum duration of less than 60 minutes.

WARNINGS

- NOT FOR INJECTION OR INTRAVENOUS INFUSION.
- Do not use unless product is clear, seal is intact and container is undamaged.
- Do not use if product is discolored or contains a precipitate.
- SINGLE patient use only. The contents of this bottle should not be used in more than one patient.
- The use of additives with this solution may cause corneal decompensation.
- This solution contains no preservative, unused contents should be discarded.

PRECAUTIONS

Open under aseptic conditions only.

Studies suggest that intraocular irrigating solutions which are iso-osmotic with normal aqueous fluids should be used with caution in diabetic patients undergoing vitrectomy since intraoperative lens changes have been observed.

There have been reports of corneal clouding or edema following ocular surgery in which Balanced Salt Solution Sterile Irrigating Solution was used as an irrigating solution.

ADVERSE REACTIONS

Irrigation or any other trauma may result in corneal swelling or bullous keratopathy.

Post-operative inflammatory reactions as well as incidents of corneal edema and corneal decompensation have been reported.

DOSAGE AND ADMINISTRATION

The irrigating solution should be used according to standard format for each surgical procedure. **Note:** Use an administration set with an air-inlet in the plastic spike since the bottle does not contain a separate airway tube. Follow directions of the particular administration set to be used. Remove the plastic cap of the Flip off closure. Clean and disinfect the rubber stopper by using a sterile alcohol wipe. Insert the spike aseptically into the bottle through the target area of the rubber stopper. Allow the fluid to flow and remove air from the tubing before irrigation begins.

HOW SUPPLIED

Balanced Salt Solution Sterile Irrigating Solution is supplied in a glass bottle using a gray butyl stopper and Flip off closure to close it.

NDC	REF	Size
Balanced Salt Solution Sterile Irrigating Solution 0264-2514-10	S2514-10	500 mL

STORAGE

Store at 20–25°C (68–77°F). Excursions permitted to 15–30°C (59–86°F). [See USP Controlled Room Temperature.] Protect from freezing.

Rx Only

Revised: November 2019

B. Braun Medical Inc.

Bethlehem, PA 18018-3524 USA

1-800-227-2862

Y36-002-943 LD-661-1

PRINCIPAL DISPLAY PANEL - 500 mL Label

Balanced Salt Solution

Sterile Irrigating Solution

REF S2514-10

NDC 0264-2514-10

500 mL

**NOT FOR I.V. USE
SINGLE USE ONLY**

B. Braun Medical Inc.

Bethlehem, PA 18018-3524 USA
1-800-227-2862

Each mL contains: sodium chloride 0.64%, potassium chloride 0.075%, calcium chloride •2H₂O 0.048%, magnesium chloride •6H₂O 0.03%, sodium acetate •3H₂O 0.39%, sodium citrate •2H₂O 0.17%, sodium hydroxide and/or hydrochloric acid (to adjust pH), and water for injection.

pH: approximately 7.0

Osmolality: approximately 300 mOsm/Kg

WARNINGS: NOT FOR INJECTION OR INTRAVENOUS INFUSION.

Do not use unless product is clear, seal is intact, vacuum is present and container is undamaged. Do not use if product is discolored or contains a precipitate. Discard unused contents. Do not use this container for more than one patient. Do not use additives with this product. Tissue damage could result if other drugs are added to product.

See package insert.

STERILE SINGLE DOSE UNIT

Storage:

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[See USP Controlled Room Temperature.]

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Rx Only

Y37-002-524 LD-662-1

LIFT
HERE

Balanced Salt Solution Sterile Irrigating Solution

REF S2514-10

NDC 0264-2514-10

500 mL

**NOT FOR I.V. USE
SINGLE USE ONLY**

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

**Balanced Salt Solution
Sterile Irrigating Solution**
SINGLE USE ONLY



NDC No. (01) 10302642514103

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Y37-002-524 LD-662-1

BALANCED SALT

sodium chloride, potassium chloride, calcium chloride, magnesium chloride, sodium acetate, and sodium citrate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0264-2514
Route of Administration	IRRIGATION		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	6.4 mg in 1 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	0.75 mg in 1 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CHLORIDE	0.48 mg in 1 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CHLORIDE	0.3 mg in 1 mL
SODIUM ACETATE (UNII: 4550K05C9B) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM ACETATE	3.9 mg in 1 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CITRATE	1.7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0264-2514-10	500 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	02/03/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091387	02/03/2010	

Labeler - B. Braun Medical Inc. (002397347)

Revised: 2/2022

B. Braun Medical Inc.