

**BALANCED SALT- sodium chloride, potassium chloride, calcium chloride, magnesium chloride, sodium acetate, and sodium citrate solution**

**B. Braun Medical Inc.**

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**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 (CaCl<sub>2</sub>·2H<sub>2</sub>O) 0.048%, magnesium chloride hexahydrate (MgCl<sub>2</sub>·6H<sub>2</sub>O) 0.03%, sodium acetate trihydrate (C<sub>2</sub>H<sub>3</sub>NaO<sub>2</sub>·3H<sub>2</sub>O) 0.39%, sodium citrate dihydrate (C<sub>6</sub>H<sub>5</sub>Na<sub>3</sub>O<sub>7</sub>·2H<sub>2</sub>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 aluminum tab. 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 aluminum closure with a tear tab.

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

Issued: November 2009

**B. Braun Medical Inc.**

Irvine, CA 92614-5895 USA

Made in USA

Y36-002-712

## PRINCIPAL DISPLAY PANEL - 500 mL Label

### Balanced Salt Solution

Sterile Irrigating Solution

NDC 0264-2514-10

REF S2514-10

**500 mL**

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

**B. Braun Medical Inc.**

Irvine, CA 92614-5895 USA

Made in USA

**Each mL contains:** sodium chloride 0.64%, potassium chloride 0.075%, calcium chloride •2H<sub>2</sub>O 0.048%, magnesium chloride •6H<sub>2</sub>O 0.03%,

sodium acetate •3H<sub>2</sub>O 0.39%, sodium citrate •2H<sub>2</sub>O 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:**

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

Y37-002-363



**BALANCED SALT**

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

**Product Information**

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

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	6.4 mg in 1 mL
<b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	0.75 mg in 1 mL
<b>CALCIUM CHLORIDE</b> (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CHLORIDE	0.48 mg in 1 mL
<b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CHLORIDE	0.3 mg in 1 mL
<b>SODIUM ACETATE</b> (UNII: 4550K0SC9B) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM ACETATE	3.9 mg in 1 mL
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CITRATE	1.7 mg in 1 mL

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0264-2514-10	12 in 1 CASE	02/03/2010	
1		500 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

### 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: 12/2018

B. Braun Medical Inc.