

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

Y36-003-042 LD-721-1

Package Insert

EXCEL® CONTAINER

Rx only

DESCRIPTION

Balanced Salt Solution Sterile Irrigating Solution is a sterile balanced salt solution in 500 mL single-dose EXCEL® flexible containers. Each mL contains sodium chloride (NaCl) 0.64%, potassium chloride (KCl) 0.075%, calcium chloride dihydrate (CaCl₂·2H₂O) 0.048%, magnesium chloride hexahydrate (MgCl₂·6H₂O) 0.03%, sodium acetate trihydrate (C₂H₃NaO₂·3H₂O) 0.39%, sodium citrate dihydrate (C₆H₅Na₃O₇·2H₂O) 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.

The EXCEL® plastic container is made from a multilayered film. The solution contact layer is a rubberized copolymer of ethylene and propylene. The container is nontoxic and biologically inert. The container-solution unit is a closed system and is not dependent upon entry of external air during administration. The container is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

Addition of medication should be accomplished using complete aseptic technique.

The closure system has two ports; the one for the administration set has a tamper evident plastic protector and the other is a medication addition site. Refer to the Directions for Use of the container.

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 overwrap is intact, 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 container should not be used in more than one patient.
- 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 to the corneal endothelium 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. Follow directions of the particular administration set to be used. 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 sterile and nonpyrogenic 500 mL single-dose EXCEL[®] flexible containers with clear overwrap, 24 per case.

Not made with natural rubber latex, PVC or DEHP.

NDC	REF	Size
Balanced Salt Solution Sterile Irrigating Solution 0264-1945-10	L2514	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.

Revised: August 2021

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Directions for Use of EXCEL[®] Container

Caution: Do not use plastic containers in series connection.

To Open

Tear overwrap down at notch and remove solution container. Check for minute leaks by squeezing solution container firmly. If leaks are found, discard solution as sterility may be impaired.

NOTE: Before use, perform the following checks:

Inspect each container. Read the label. Ensure solution is the one ordered and is within the expiration date. Invert container and carefully inspect the solution in good light for cloudiness, haze, or particulate matter. Any container which is suspect should not be used.

Use only if solution is clear and container and seals are intact.

Preparation for Administration

1. Remove plastic protector from sterile set port at bottom of container.
2. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Warning: Some additives may be incompatible.

To Add Medication Before Solution Administration

1. Prepare medication site.
2. Using syringe with 18–22 gauge needle, puncture medication port and inner diaphragm and inject.
3. Squeeze and tap ports while ports are upright and mix solution and medication thoroughly.

To Add Medication During Solution Administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 18–22 gauge needle of appropriate length (at least 5/8 inch), puncture resealable medication port and inner diaphragm and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by tapping and squeezing them while container is in the upright position.

6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

B. Braun Medical Inc.

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

PRINCIPAL DISPLAY PANEL - 500 mL Label

**Balanced Salt Solution
Sterile Irrigating Solution**

**NOT FOR INTRAVENOUS USE
SINGLE USE ONLY**

REF L2514

NDC 0264-1945-10

**500 mL
EXCEL® CONTAINER**

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pH: approximately 7.0; Osmolality: approximately 300 mOsm/Kg

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Do not use

this container for more than one patient. See package insert.

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[See USP Controlled Room Temperature.]

Protect from freezing.

Not made with natural rubber latex, PVC or DEHP.

Rx only

Y94-003-436 LD-720-1

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Balanced Salt Solution

Sterile Irrigating Solution

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NDC 0264-1945-10

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Rx only 

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CODE

BARCODE

BARCODE

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

EXP

LOT

Y94-003-436

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:0264-1945
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:0264-1945-10	500 mL in 1 BAG; Type 0: Not a Combination Product	01/28/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA091387	01/28/2022		

Labeler - B. Braun Medical Inc. (002397347)

Revised: 3/2024

B. Braun Medical Inc.