

**BSS - balanced salt solution solution**  
**Alcon Laboratories, Inc.**

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**BSS®**  
**Sterile Irrigating Solution**  
**(balanced salt solution)**

**DESCRIPTION:**

BSS® 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 7.5. The osmolality is approximately 300 mOsm/Kg.

**CLINICAL PHARMACOLOGY:**

BSS 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 bag 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.

Prior to use, check the following: tip should be firmly in place, irrigating needle should be properly seated; squeeze out several drops before inserting into anterior chamber. The needle should be removed from the anterior chamber prior to releasing pressure to prevent suction.

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 and edema following ocular surgery in which BSS 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 adapter plug is designed to accept an irrigating needle. Tissues may be irrigated by attaching the needle to the DROP-TAINER® bottle as explained below. External irrigation may be done without the irrigating needle.

Method of using Adapter Plug for LUER-LOK® Hub Ophthalmic Irrigating Needle:

1. Aseptically remove DROP-TAINER bottle from blister by peeling paper backing.
2. Snap on surgeon's sterile irrigation needle. Push until rmly in place and twist slightly.
3. Test assembly for proper function before use.

**NOTE:** LUER-LOK is a registered trademark of Becton, Dickinson and Company.

## **HOW SUPPLIED**

In 15 mL and 30 mL sterile DROP-TAINER® bottles (consisting of a polypropylene bottle and LUER-LOK® adapter plug with a white polypropylene closure) in a blister package.

15 mL in a 15 mL bottle:

NDC 0065-0795-15

30 mL in a 30 mL bottle

NDC 0065-0795-30

STORAGE:Store at 36°-77°F (2°-25°C).

Revised: November 2015

**Alcon®**

A Novartis company

Distributed by:

**Alcon Laboratories, Inc.**

6201 South Freeway

Fort Worth, Texas 76134 USA

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W9012634-1115

## **PRINCIPAL DISPLAY PANEL**

### **SINGLE PATIENT USE ONLY**

**Rx Only**

**NDC 0065-1795-04**

**BSS®**

**Sterile Irrigating Solution**

(balanced salt solution)

**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. The pH is

approximately 7.5. The osmolality is approximately 300 mOsm/Kg.

**NOT FOR I.V. USE**

**Read accompanying insert.**

**WARNINGS:** NOT FOR INJECTION OR INTRAVENOUS INFUSION. Do not use unless outer overwrap is intact, product is clear, seal is intact and bag is undamaged. Do not use if product is discolored or contains a precipitate. Discard unused contents. Do not use this bag for more than one patient.

**STORAGE:** Store at 36° - 77° F (2° - 25°C).

**STERILE      500 mL**

**Alcon®**

**Alcon Laboratories, Inc.**

Fort Worth, Texas 76134 USA

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**LOT:**

**EXP.:**

**MFD.:**

**9012630-1115**

LOT:  
EXP.:  
MFD.:



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## SINGLE PATIENT USE ONLY

Rx Only

NDC 0065-1795-04

### **BSS<sup>®</sup>** **Sterile Irrigating Solution** (balanced salt solution)

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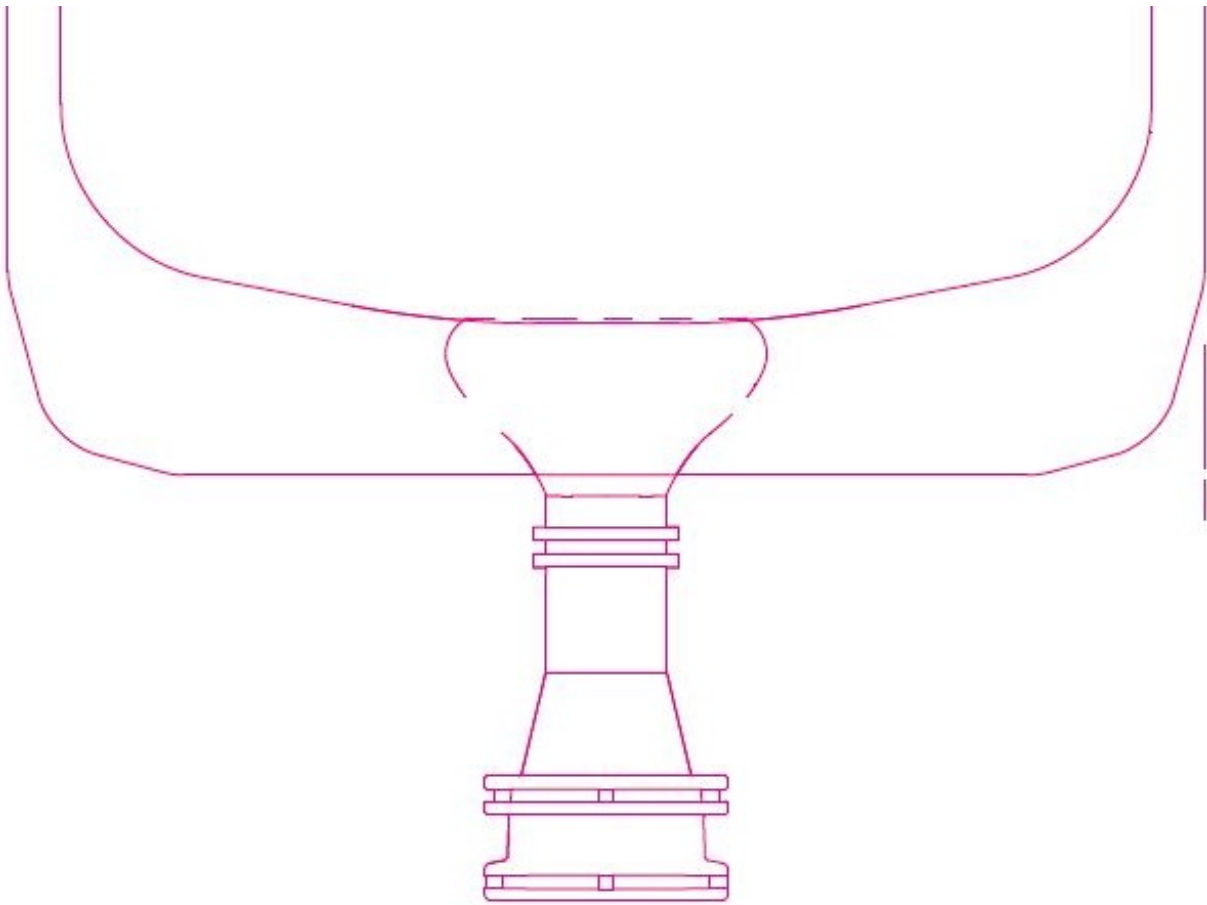
**STERILE**      **500 mL**

**Alcon<sup>®</sup>**

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Fort Worth, Texas 76134 USA

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Storage: Store at 36° - 77°F (2° - 25°C).

Do not use unless outer overwrap is intact.

**9012629-1115**

Storage: Store at 36° - 77°F (2° - 25°C).

Do not use unless outer overwrap is intact.

9012629-1115

## BSS

balanced salt solution solution

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0065-1795
Route of Administration	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	6.4 mg in 1 mL
<b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98H10) (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	
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-1795-04	500 mL in 1 BAG; Type 0: Not a Combination Product	03/28/1969	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA020742	03/28/1969	

**Labeler** - Alcon Laboratories, Inc. (008018525)

**Registrant** - Alcon Laboratories, Inc. (008018525)

Establishment			
Name	Address	ID/FEI	Business Operations
Alcon Research Ltd		007672236	MANUFACTURE(0065-1795)