

BSS- balanced salt solution solution

Alcon Laboratories, Inc.

Reference Label Set Id: 4bd4d59c-eb3b-4a5e-9eb7-ae95b0a92bea

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, vacuum is present 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.
- 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 and edema following ocular surgery in which BSS 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

This 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 blue flip-off cap. 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

BSS® Sterile Irrigating Solution is supplied in a glass bottle using a grey butyl stopper and aluminum seal with a blue polypropylene flip-off cap.

250 mL in a 325 mL container: **NDC 0065-0795-25.**

500 mL in a 635 mL container: **NDC 0065-0795-50.**

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

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Distributed by:

Alcon Laboratories, Inc.

Fort Worth, Texas 76134

USA

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PRINCIPAL DISPLAY PANEL

NDC 0065-0795-50

BSS®

Sterile Irrigating Solution

(balanced salt solution)

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

STERILE 500 mL

Rx Only

NOT FOR I.V. USE

SINGLE DOSE UNIT

Read accompanying insert.

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.

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

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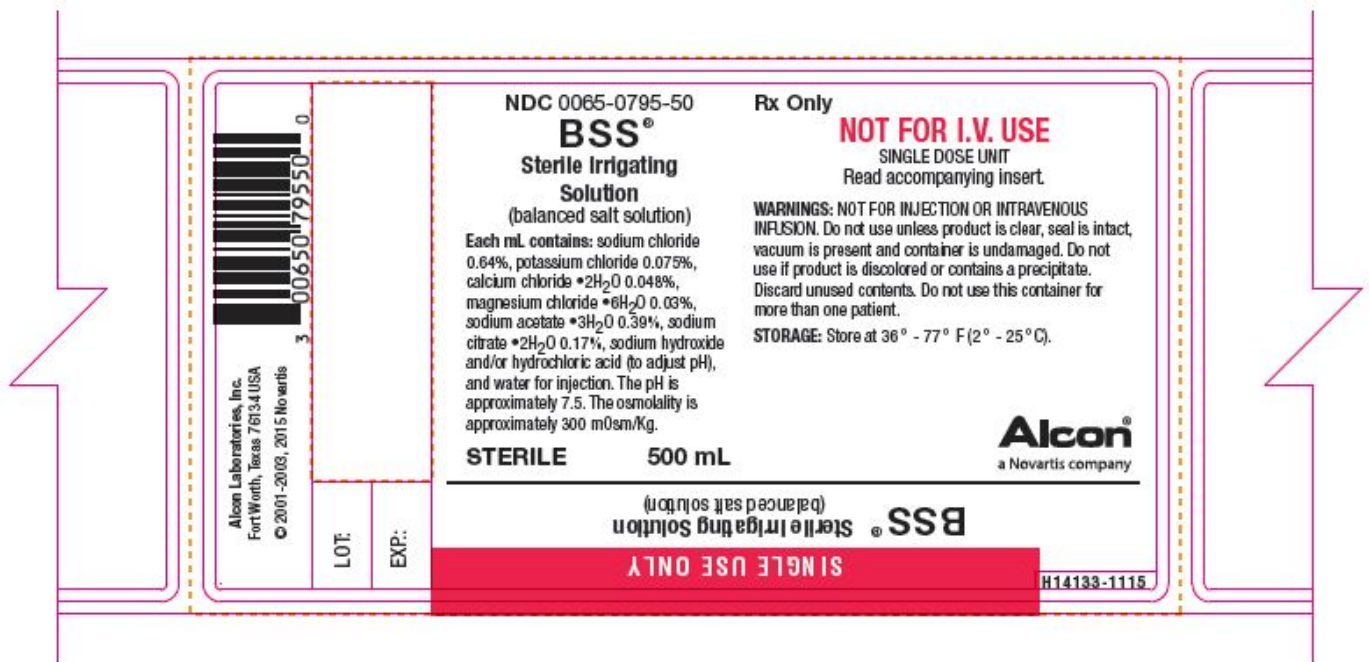
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Fort Worth, Texas 76134 USA
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SINGLE USE ONLY

Lot:

Exp.:

H14133-1115



BSS

balanced salt solution solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0065-0795
Route of Administration	OPHTHALMIC		

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: 4550K0SC9B) (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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-0795-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/1969	02/28/2018
2	NDC:0065-0795-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product		

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(0065-0795)

Revised: 1/2016

Alcon Laboratories, Inc.