BSS- balanced salt solution solution
Alcon Laboratories, Inc.
Reference Label Set Id: d2f55b3f-0873-4536-aedb-2829a91927c7
-------

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 (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 7.5. 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 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.
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 or 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 firmly 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 LEURLOK® 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
©2000-2003, 2015 Novartis
9012634-1115

**PRINCIPAL DISPLAY PANEL**

**NDC** 0065-0795-15

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

**ALCON®**
a Novartis company

CONTENTS: 3 doz. 15mL Single Dose Bottles

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

Rx Only
NDC 0065-0795-15

BSS®
Sterile Irrigating Solution
(balanced salt solution)

STERILE UNLESS PACKAGE OPEN OR BROKEN

15 mL DROP-TAINER® Bottle, SINGLE DOSE UNIT With Adapter for LUER-LOK® Hub Irrigating Needle

A sterile balanced salt solution for extraocular and intraocular use during procedures with an expected maximum duration of less than 60 minutes. Read enclosed insert.

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 blister or paper backing is damaged or broken.
• 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.

Rx Only

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

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

NOTE: Luer-Lok is a registered trademark of Becton, Dickinson & Co.
NDC 0065-0795-15

BSS®

STERILE IRRIGATING SOLUTION

(BALANCED SALT SOLUTION)
BSS®
STERILE IRRIGATING SOLUTION
(BALANCED SALT SOLUTION)
UNIT DOSE
15 mL

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

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X)</td>
<td>SODIUM CHLORIDE</td>
<td>6.4 mg in 1 mL</td>
</tr>
<tr>
<td>POTASSIUM CHLORIDE (UNII: 660YQ98I10)</td>
<td>POTASSIUM CHLORIDE</td>
<td>0.75 mg in 1 mL</td>
</tr>
<tr>
<td>CALCIUM CHLORIDE (UNII: M4I0D6VV5M)</td>
<td>CALCIUM CHLORIDE</td>
<td>0.48 mg in 1 mL</td>
</tr>
<tr>
<td>MAGNESIUM CHLORIDE (UNII: 02F3473H3O)</td>
<td>MAGNESIUM CHLORIDE</td>
<td>0.3 mg in 1 mL</td>
</tr>
<tr>
<td>SODIUM ACETATE (UNII: 4550K05C9B)</td>
<td>SODIUM ACETATE</td>
<td>3.9 mg in 1 mL</td>
</tr>
<tr>
<td>SODIUM CITRATE (UNII: 1Q73Q2JULR)</td>
<td>SODIUM CITRATE</td>
<td>1.7 mg in 1 mL</td>
</tr>
</tbody>
</table>
# Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM HYDROXIDE (UNII: 55X04QC32I)</td>
<td></td>
</tr>
<tr>
<td>HYDROCHLORIC ACID (UNII: QTT17582CB)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
</tbody>
</table>

## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0065-0795-15</td>
<td>15 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>03/28/1969</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0065-0795-30</td>
<td>30 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>03/28/1969</td>
<td>12/31/2018</td>
</tr>
<tr>
<td>3</td>
<td>NDC:0065-0795-25</td>
<td>250 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>03/28/1969</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NDC:0065-0795-50</td>
<td>500 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>03/28/1969</td>
<td></td>
</tr>
</tbody>
</table>

## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020742</td>
<td>03/28/1969</td>
<td></td>
</tr>
</tbody>
</table>

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

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

## Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcon Research Ltd</td>
<td></td>
<td>007672236</td>
<td>MANUFACTURE(0065-0795)</td>
</tr>
</tbody>
</table>

Revised: 1/2016