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I. Package Insert for 250 mL and 500 mL glass bottles

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, 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

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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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II. Container label for 250 mL glass bottle

NDC 0065-0795-25

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 250 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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SINGLE USE ONLY

BSS*

Sterile Irrigating Solution

(balanced salt solution)

A170506-0915

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III. Container label for 500 mL glass bottle

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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SINGLE USE ONLY

BSS*

Sterile Irrigating Solution
(balanced salt solution)

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IV. Package Insert for 500 mL flexible plastic container

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 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.
- 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.

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. Follow directions of the particular administration set to be used. Remove the outer overwrap. Clean and disinfect the rubber stopper by using a sterile alcohol wipe. Insert the spike aseptically into the bag through the target area of the rubber stopper. Allow the fluid to flow and remove air from the tubing before irrigation begins.

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HOW SUPPLIED: BSS* Sterile Irrigating Solution is supplied in a clear polypropylene bag using a grey butyl stopper and aluminum seal packaged in a clear, multilayered plastic outer overwrap. 500 mL in a bag: NDC 0065-1795-04.

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

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V. Container label for 500 mL flexible plastic container

LOT:
EXP.:
MFD.:

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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 •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.

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

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VI. Bag Overwrap for 500 mL flexible plastic container

Storage: Store at 36° - 77°F (2° - 25°C).
Do not use unless overwrap is intact.

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VII. Package Insert for the 15 mL and 30 mL DROPTAINER dispenser bottles

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 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. Postoperative inflammatory reactions as well as incidents of corneal edema and corneal decompensation have been reported.

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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).

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VIII. Backing Paper for 15 mL DROPTAINER dispenser bottles

NDC 0065-0795-15

BSS*

Sterile Irrigating Solution

(balanced salt solution)

STERILE UNLESS PACKAGE OPEN OR BROKEN

15mL 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 dehydrate 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.

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IX. Backing Paper for 30 mL DROPTAINER dispenser bottles

NDC 0065-0795-30

BSS*

Sterile Irrigating Solution

(balanced salt solution)

STERILE UNLESS PACKAGE OPEN OR BROKEN

30mL 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.

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X. 15 mL DROPTAINER dispenser bottles packer – 3 dozen 15 mL single dose bottles

NDC 0065-0795-15

BSS*

Sterile Irrigating Solution

(balanced salt solution)

CONTENTS: 3 doz. 15mL Single Dose Bottles

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

Rx Only

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BSS*

Sterile Irrigating Solution

(balanced salt solution)

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CONTENTS: 3 doz. 15mL Single Dose Bottles

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NDC 0065-0795-15

BSS*

Sterile Irrigating Solution

(balanced salt solution)

NDC 0065-0795-15

BSS*

Sterile Irrigating Solution

(balanced salt solution)

Alcon®

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CONTENTS: 3 doz. 15mL Single Dose Bottles

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NDC 0065-0795-15

BSS*

Sterile Irrigating Solution

(balanced salt solution)

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XI. 30 mL DROPTAINER dispenser bottles packer – 3 dozen 30 mL single dose bottles

NDC 0065-0795-30

BSS*

Sterile Irrigating Solution

(balanced salt solution)

CONTENTS: 20 x 30mL Single Dose Bottles. STORAGE: Store at 36°-77° F (2°-25°C).

Rx Only

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LOT:

EXP:

NDC 0065-0795-30

BSS*

Sterile Irrigating Solution

(balanced salt solution)

Alcon®

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CONTENTS: 20 x 30mL Single Dose Bottles

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NDC 0065-0795-30

BSS*

Sterile Irrigating Solution

(balanced salt solution)

NDC 0065-0795-30

BSS*

Sterile Irrigating Solution

(balanced salt solution)

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CONTENTS: 20 x 30mL Single Dose Bottles

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BSS*

Sterile Irrigating Solution

(balanced salt solution)

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