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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 package is clear, seal is intact, 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.
- The use of additives with this solution may cause corneal decompensation.
- 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 BSS Sterile Irrigating Solution was used as an irrigating solution.

ADVERSE REACTIONS: Irrigation or any 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 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° to 77°F (2° to 25°C). DO NOT FREEZE.

Rx Only

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BSS 500mL Label

<p>BSS Sterile Irrigating Solution (balanced salt solution)</p> <p style="text-align: right;">NDC 0065-0795-50</p>		
<p>Lot:</p> <p>Exp:</p> <p>Barcode</p>	<p>Each mL containing 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.</p> <p>STERILE 500 mL</p> <p>Single Use Only</p>	<p>Rx Only NOT FOR IV USE SINGLE DOSE UNIT Read accompanying 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 product is discolored or contains a precipitate. Discard unused contents. Do not use this container on more than one patient. Do not use additives with this product. Tissue damage could result if other drugs are added to product.</p> <p>STORAGE: Store at 36°- 77°F (2° - 25°C). DO NOT FREEZE.</p> <p>ALCON LOGO Alcon Laboratories, Inc. Fort Worth Texas 76134 USA Printed in USA ©2002 Alcon, Inc. Part Number-Revision Date</p>

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BSS 250 mL Label

BSS Sterile Irrigating Solution (balanced salt solution)		NDC 0065-0795-25
Lot:	Each mL containing sodium chloride 0.64%, potassium chloride 0.075%, calcium chloride ·2H ₂ O 0.048%, magnesium chloride ·6H ₂ O 0.03%, sodium acetate ·3H ₂ O 0.39%, sodium citrate ·2H ₂ 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. STERILE 250 mL Single Use Only	Rx Only NOT FOR IV USE SINGLE DOSE UNIT Read accompanying 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 product is discolored or contains a precipitate. Discard unused contents. Do not use this container on more than one patient. Do not use additives with this product. Tissue damage could result if other drugs are added to product.
Exp:		STORAGE: Store at 36°- 77°F (2° - 25°C). DO NOT FREEZE.
Barcode		ALCON LOGO Alcon Laboratories, Inc. Fort Worth Texas 76134 USA Printed in USA ©2002 Alcon, Inc. Part Number-Revision Date