

NDA 018469/S-056

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**Labeling for BSS PLUS 250 mL (Part I) and 10 mL (Part II) Bottle kit  
BSS PLUS 250 mL (Part I) container label**

250mL

Single Patient Use

NDC 0065-0800-25

**BSS PLUS\***

**STERILE INTRAOCULAR IRRIGATING SOLUTION**

(balanced salt solution enriched with bicarbonate, dextrose and glutathione)

**After addition of BSS PLUS\*-** Part II (10 mL), each mL contains: sodium chloride 7.14 mg, potassium chloride 0.38 mg, calcium chloride dihydrate 0.154 mg, magnesium chloride hexahydrate 0.2 mg, dibasic sodium phosphate 0.42 mg, sodium bicarbonate 2.1 mg, dextrose 0.92 mg, glutathione disulfide (oxidized glutathione) 0.184 mg, hydrochloric acid and/or sodium hydroxide (to adjust pH), in water for injection.

pH Approx. 7.4 - Osmolality Approx. 305 mOsm/kg

**Rx Only**

**WARNINGS:** FOR IRRIGATION DURING OPHTHALMIC SURGERY ONLY. 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.

**PRECAUTIONS:** DO NOT USE **BSS PLUS** UNTIL PART I IS FULLY RECONSTITUTED WITH PART II.

DISCARD UNUSED CONTENTS SIX HOURS AFTER PREPARATION.  
DO NOT USE THIS CONTAINER FOR MORE THAN ONE PATIENT.

**Reconstitute just prior to use in surgery**

\* a trademark of Novartis

**Alcon®**

**a Novartis company**

**Alcon Laboratories, Inc.**

Fort Worth, Texas 76134 USA

Patient:

Reconstituted at

AM/PM on

**SINGLE USE ONLY**

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**LOT:**

**EXP:**

240mL

**NDC 0065-0800-25**

**BSS PLUS\* PART I  
STERILE SOLUTION**

(For Reconstitution by Addition of BSS PLUS\* Concentrate Part II, 10 mL)\*\*

Each mL contains: sodium chloride 7.44 mg, potassium chloride 0.395 mg, dibasic sodium phosphate 0.433 mg, sodium bicarbonate 2.19 mg, hydrochloric acid and/or sodium hydroxide (to adjust pH), in water for injection.

**Rx Only**

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

**WARNINGS:** FOR IRRIGATION DURING OPHTHALMIC SURGERY ONLY AFTER RECONSTITUTION. DO NOT USE UNLESS PRODUCT IS CLEAR, SEAL IS INTACT, VACUUM IS PRESENT AND CONTAINER IS UNDAMAGED.

**NOT FOR INJECTION OR INTRAVENOUS INFUSION.**

**\*\*Reconstitute just prior to use in surgery. Remove this part of label after reconstitution. Read the Preparation and Administration sections of the package insert before reconstitution for important directions and precautions.**

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**Labeling for BSS PLUS 500 mL (Part I) and 20 mL (Part II) Bottle kit  
BSS PLUS 500 mL (Part I) container label**

500mL

Single Patient Use

NDC 0065-0800-50

**BSS PLUS\***

**STERILE INTRAOCULAR IRRIGATING SOLUTION**

(balanced salt solution enriched with bicarbonate, dextrose and glutathione)

**After addition of BSS PLUS\*-** Part II (20 mL), each mL contains: sodium chloride 7.14 mg, potassium chloride 0.38 mg, calcium chloride dihydrate 0.154 mg, magnesium chloride hexahydrate 0.2 mg, dibasic sodium phosphate 0.42 mg, sodium bicarbonate 2.1 mg, dextrose 0.92 mg, glutathione disulfide (oxidized glutathione) 0.184 mg, hydrochloric acid and/or sodium hydroxide (to adjust pH), in water for injection.

pH Approx. 7.4 - Osmolality Approx. 305 mOsm/kg

**Rx Only**

**WARNINGS:** FOR IRRIGATION DURING OPHTHALMIC SURGERY ONLY. 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.

**PRECAUTIONS:** DO NOT USE **BSS PLUS** UNTIL PART I IS FULLY RECONSTITUTED WITH PART II.

DISCARD UNUSED CONTENTS SIX HOURS AFTER PREPARATION.  
DO NOT USE THIS CONTAINER FOR MORE THAN ONE PATIENT.

**Reconstitute just prior to use in surgery**

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Patient:

Reconstituted at

AM/PM on

**SINGLE USE ONLY**

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**LOT:**

**EXP:**

480mL

**NDC** 0065-0800-50

**BSS PLUS\* PART I  
STERILE SOLUTION**

(For Reconstitution by Addition of BSS PLUS\* Concentrate Part II, 20 mL)\*\*

Each mL contains: sodium chloride 7.44 mg, potassium chloride 0.395 mg, dibasic sodium phosphate 0.433 mg, sodium bicarbonate 2.19 mg, hydrochloric acid and/or sodium hydroxide (to adjust pH), in water for injection.

**Rx Only**

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

**WARNINGS:** FOR IRRIGATION DURING OPHTHALMIC SURGERY ONLY AFTER RECONSTITUTION. DO NOT USE UNLESS PRODUCT IS CLEAR, SEAL IS INTACT, VACUUM IS PRESENT AND CONTAINER IS UNDAMAGED.

**NOT FOR INJECTION OR INTRAVENOUS INFUSION.**

**\*\*Reconstitute just prior to use in surgery. Remove this part of label after reconstitution. Read the Preparation and Administration sections of the package insert before reconstitution for important directions and precautions.**

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