

Balanced Salt Solution
Sterile

DESCRIPTION: Balanced Salt 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: Balanced Salt 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 Balanced Salt 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.

DOSAGE AND ADMINISTRATION: The irrigating solution should be used according to standard format for each surgical procedure. **Note:** Pull the tab to remove the outer aluminum ring and dust cover. Insert the bottle into the AquaLase™ Liquefaction Device. See the equipment directions for specific instructions.

HOW SUPPLIED:

90 mL of solution in a 100 mL polypropylene single dose bottle which contains a collapsible polypropylene bag with a rubber stopper and aluminum seal.

NDC 0065-0795-90

STORAGE: Store at 36° to 77°F (2° to 25°C). DO NOT FREEZE.

Rx Only

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