

500ml

Balance Salt Solution (For Irrigation) Sterile

SURESOL™

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STERILE NON-PYROGENIC SINGLE DOSE CONTAINER

STERILE INTRAOCULAR IRRIGATING SOLUTION

COMPOSITION:

Each 100 ml contains:

Sodium Chloride I.P. 0.490% w/v

Potassium Chloride I.P. 0.075% w/v

Calcium Chloride I.P. 0.048% w/v

Magnesium Chloride I.P. 0.030% w/v

Sodium Acetate I.P. 0.390% w/v

Sodium Citrate I.P. 0.170% w/v

Water For Injection I.P. Q.S.

CAUTION: Not to be used if container is found leaking or solution is not clear or contains visible particles.

DESCRIPTION: SURESOL is a sterile intraocular irrigating solution for use during intraocular surgical procedures.

CLINICAL PHARMACOLOGY: Suresol is specially made for ocular surgeries with a composition that matches aqueous humor pH & osmolarity. It is a Lactate free solution with least chance of bacterial/fungal growth and least chances of corneal edema.

None of the components of SURESOL are foreign to the eye, and SURESOL has no pharmacological action. SURESOL is an irrigation solution for providing corneal detumescence and maintaining corneal endothelial integrity during intraocular perfusion.

Balanced Salt Solution are more suitable than normal saline as it contains the appropriate pH and ionic composition necessary for the maintenance of normal retinal activity. Balanced Salt Solution have been demonstrated to be safe and effective when used during surgical procedures such as pars plana vitrectomy, phacoemulsification, cataract extraction/lens aspiration, anterior segment reconstruction.

INDICATIONS: SURESOL is indicated for use as an intraocular irrigating solution during intraocular surgical procedures involving perfusion of the eye.

CONTRAINDICATIONS: There are no specific contraindications to the use of SURESOL

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: Discard unused contents. SURESOL does not contain a preservative; therefore, do not use this container for more than one patient.

ADVERSE REACTIONS: Postoperative inflammatory reactions as well as incidents of corneal edema and corneal decompensation have been reported. Their relationship to the use of Balanced Salt Solution has not been established.

OVERDOSAGE: The solution has no pharmacological action and thus no potential for overdose. However, as with any intraocular surgical procedure, the duration of intraocular manipulation should be kept to a minimum.

DOSAGE AND ADMINISTRATION: The solution should be used according to the standard technique employed by the operating surgeon.

SURESOL: INSTRUCTIONS FOR USE

- 1 – Suresol is sterile & ready to use solution for ophthalmic surgeries – autoclaving is not recommended.
- 2 – Remove the polythene cover of the bottle.
- 3 – Please do thorough visual inspection before using – if any particle or turbidity is seen – discard the bottle which will be replaced with a new bottle.
- 4 – Pull the plastic cover of the port to open.
- 5 – Insert the spike of tubing with bottle in 'upright position' & ensure it is fixed properly as there is an additional poly-propylene seal under the rubber which needs to be broken.
- 6 – The size & thickness of spike is different for different machines.
- 7 – Keep the other end of tubing open for air passage else the spike might not fit properly & come out due to positive pressure inside the bottle.
- 8 – If the fluid flow rate is less than required, increasing the bottle height might help.
- 9 – If the flow rate is still less, putting an air – vent will optimize flow rate.
- 10 – Extra medication can be added to the solution through the second port in the bottle.

HOW SUPPLIED: SURESOL is supplied in 500 ml Bottle with Steriport Technology from Amanta. SURESOL Bottle is made from Polypropylene, which is a FDA approved material that is transparent for easy visual inspection, light weight for easy handling and is sterilized at 121°C

for 20 min at 1.3 psi. It is latex free and has a two port closed irrigation system, with least risk of contamination.

STORAGE: Store below 30° C in a cool, dry place. Protect from light. Do not freeze. Keep the medicine out of reach of children.

SURESOL™: Trade Mark of Lavue

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Marketed by:



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