

PRESCRIBING INFORMATION

ODAN BALANCED SALT SOLUTION

Sterile Physiological irrigating Solution

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ODAN BALANCED SALT SOLUTION Sterile Physiological Irrigating Solution

DESCRIPTION

ODAN BALANCED SALT SOLUTION is a lint-free solution containing essential ions for normal cell metabolism. Each mL of ODAN BALANCED SALT SOLUTION contains: Calcium Chloride 0.48 mg, Magnesium Chloride 0.30mg, Potassium Chloride 0.75 mg, Sodium Acetate 3.90 mg, Sodium Chloride 6.40 mg, Sodium Citrate 1.70 mg, Hydrochloric acid and/or Sodium Hydroxide (to adjust pH) and water for injection. The pH is approximately 7.5. The osmolality is approximately 300 mOsm/Kg.

CLINICAL PHARMACOLOGY

ODAN BALANCED SALT SOLUTION is a sterile isotonic solution for use in irrigating tissues of the eyes.

INDICATIONS AND USAGE

For irrigation of eyes, ears, nose and/or throat during a variety of surgical procedures.

WARNING

NOT FOR INJECTION OR INTRAVENOUS INFUSION.

SINGLE patient use only. Do not use the contents of the bottle in more than one patient. The solution contains no preservatives, discard unused portion. The use of additives with this solution may cause corneal decompensation.

PRECAUTIONS

This solution is preservative free and should be discarded after a single use. Do not use this solution unless it is clear or if precipitate is visible. Do not use if seal assembly or bottle is damaged.

ADVERSE REACTIONS

Bullous keratopathy may result when abnormal corneal endothelium is irrigated or subjected to any other trauma.

DOSAGE AND ADMINISTRATION

This irrigating solution should be used in conjunction with established practices for each surgical procedure. An administration set equipped with an air inlet device in the plastic spike should be used since the container does not have an airway tube. Flip off plastic cap from the aluminium seal assembly. Using aseptic technique it is recommended to insert the spike through the large circular, indented area of the rubber plug. Allow the fluid to flow and remove air from the tubing before irrigation begins.

PACKAGING

ODAN BALANCED SALT SOLUTION is available in single use glass bottles of 250 mL and 500 mL.

STORAGE

Store between 2°C and 30°C. Avoid exposure to excessive heat and protect from freezing.