

Amnealyte Duo™

Multiple Electrolytes Injection Type 1 USP

500 ml

Abridged Prescribing Information:

AMNEALYTE DUO® Multiple Electrolytes Injection Type 1 USP (500 mL)

Composition: Each 100 mL contains: Sodium Chloride I.P., 0.526 g; Sodium Gluconate USP, 0.502 g; Sodium Acetate Trihydrate I.P., 0.368 g; Potassium Chloride I.P., 0.037 g; Magnesium Chloride Hexahydrate I.P., 0.030 g; Water for Injection I.P., q.s. It may contain Sodium Hydroxide I.P. or Hydrochloric Acid I.P. to adjust the pH. DESCRIPTION: AMNEALYTE DUO® is a sterile, nonpyrogenic isotonic solution in a single dose plastic container for intravenous administration. INDICATIONS : Indicated as a source of water and electrolytes or as an alkalinizing agent. Mainly used for volume replacement therapy in hypovolemic shocks. DOSAGE AND ADMINISTRATION: Intended for intravenous administration using sterile equipment. AMNEALYTE DUO® is compatible with blood or blood components. It may be administered prior to or following the infusion of blood through the same administration set (i.e., as a priming solution), added to or infused concurrently with blood components, or used as a diluent in the transfusion of packed erythrocytes. AMNEALYTE DUO® are equally compatible with blood or blood components. The choice of product, dosage, volume, rate, and duration of administration is dependent upon the age, weight and clinical condition of the patient and concomitant therapy, and administration should be determined by a physician experienced in intravenous fluid therapy. Additives may be incompatible. Evaluate all additions to the plastic container for compatibility and stability of the resulting preparation. After addition, if there is a discoloration and/or the appearance of precipitates, insoluble complexes or crystals, do not use. Do not store solutions containing additives. Discard any unused portion. CONTRAINDICATIONS: AMNEALYTE DUO® is contraindicated in patients with a known hypersensitivity to the product. ADVERSE REACTIONS: Tachycardia, chest pain, chest discomfort, dyspnea, flushing, hyperemia, asthenia, pyrexia, hypotension, wheezing, urticaria, cold sweat, chills, infusion site pain, burning sensation, hyperkalemia, hyponatremia and hyponatremic encephalopathy. WARNINGS : Hypersensitivity and infusion reactions have been reported with AMNEALYTE DUO®. Stop the infusion immediately if signs or symptoms of a hypersensitivity reaction develop. such as tachycardia, chest pain, dyspnea and flushing. Fluid Overload: Depending on the volume and rate of infusion, the intravenous administration of AMNEALYTE DUO® can cause electrolyte disturbances such as overhydration, and congested states, including pulmonary congestion and edema. Hyponatremia: AMNEALYTE DUO® may cause hyponatremia. Hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy, and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury. Hypermagnesemia: Hypermagnesemia may occur with AMNEALYTE DUO®. Conditions that may increase the risk of hypernatremia, fluid overload and edema (central and peripheral), include patients with primary hyperaldosteronism; secondary hyperaldosteronism associated with, for example, hypertension, congestive heart failure, liver disease (including cirrhosis), renal disease (including renal artery stenosis, nephrosclerosis); and pre-eclampsia. Hypermagnesemia: AMNEALYTE DUO® is not indicated for the treatment of hypomagnesemia. Acidosis: AMNEALYTE DUO® is not for use for the treatment of lactic acidosis or severe metabolic acidosis in patients with severe liver and/or renal impairment. Alkalosis: AMNEALYTE DUO® is not indicated for the treatment of hypochloremic hypokalemic alkalosis. Avoid use in patients with hypochloremic hypokalemic alkalosis. Hypocalcemia: AMNEALYTE DUO® contains no calcium, and an increase in plasma pH due to its alkalinizing effect may lower the concentration of ionized (not protein-bound) calcium. Avoid AMNEALYTE DUO® in patients with hypocalcemia. Hyperkalemia: Potassium-containing solutions, including AMNEALYTE DUO® may increase the risk of hyperkalemia. PRECAUTIONS: In patients with renal impairment, administration of AMNEALYTE DUO® may result in sodium and/or potassium or magnesium retention. AMNEALYTE DUO® in patients with severe renal impairment or conditions that may cause sodium and/or potassium retention or magnesium retention, fluid overload, or edema. If use cannot be avoided, monitor patients with severe renal impairment for development of these adverse reactions. STORAGE: Store at a temperature not exceeding 30°C. Discard Unused Portion. PRESENTATION: AMNEALYTE DUO® in plastic container is available in AMNEALYTE DUO® 500 ml in Single-dose Container.



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