Amnealyte

Multiple Electrolytes Injection Type 1 USP

1000 ml

Abridged Prescribing Information:

AMNEALYTE® Multiple Electrolytes Injection Type 1 USP (500 ml and 1000 ml)

Presentation: 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. AMNEALYTE® administered intravenously has value as a source of water, electrolytes, and calories.Dosage and administration: AMNEALYTE® is intended for intravenous administration using sterile equipment. Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container. Set the vent to the closed position on a vented intravenous administration set to prevent air embolism. Use a dedicated line without any connections to avoid air embolism. Do not pressurize intravenous solutions contained in flexible plastic containers to increase flow rates in order to avoid air embolism due to incomplete evacuation of residual air in the container. Prior to infusion, visually inspect the solution for particulate matter and discoloration. The solution should be clear and there should be no precipitates. Do not administer unless solution is clear, and container is undamaged. AMNEALYTE® 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® are equally compatible with blood or blood components. Dosing Information: 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. Introduction of Additives: Additives may be incompatible. Evaluate all additions to the plastic container for compatibility and stability of the resulting preparation. Consult with a pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. 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. Indication: As a source of water and electrolytes or as an alkalinizing agent. Mainly used for volume replacement therapy in hypovolemic shocks. Contraindications: In patients with a known hypersensitivity to the product. Warnings & precautions: Hypersensitivity Reactions Stop the infusion immediately if signs or symptoms of a hypersensitivity reaction develop. Intravenous administration of AMNEALYTE®. Avoid AMNEALYTE® in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor fluid balance, electrolyte concentrations, and acid base balance, as needed and especially during prolonged use. Hyponatremia AMNEALYTE® may cause hyponatremia. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury. The risk of hospital-acquired hyponatremia is increased in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH) treated with high volume of hypotonic AMNEALYTE®. Avoid AMNEALYTE® in hypervolemic or overhydrated patients. If use cannot be avoided, monitor serum sodium concentrations. Hypernatremia. Certain medications, such as corticosteroids or corticotropin, may also increase risk of sodium and fluid retention. Avoid AMNEALYTE® in patients with, or at risk for, hypernatremia. If use cannot be avoided, monitor serum sodium concentrations. Hypermagnesemia Avoid solutions containing magnesium including AMNEALYTE® in patients with or predisposed to hypermagnesemia, including patients with severe renal impairment and those patients receiving magnesium therapy (e.g., treatment of eclampsia and myasthenia gravis). AMNEALYTE® is not indicated for the treatment of hypomagnesemia. Acidosis AMNEALYTE® is not for use for the treatment of lactic acidosis or severe metabolic acidosis in patients with severe liver and/or renal impairment. Alkalosis Excess administration of AMNEALYTE® can result in metabolic alkalosis. Avoid AMNEALYTE® in patients with alkalosis or at risk for alkalosis. AMNEALYTE® is not indicated for the treatment of hypochloremic hypokalemic alkalosis. Avoid use in patients with hypochloremic hypokalemic alkalosis. Hypocalcemia AMNEALYTE® 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® in patients with hypocalcemia. Hyperkalemia Potassium-containing solutions, including AMNEALYTE® may increase the risk of hyperkalemia. Patient's at increased risk of developing hyperkalemia include those: With conditions predisposing to hyperkalemia and/or associated with increased sensitivity to potassium, such as patients with severe renal impairment, acute dehydration, extensive tissue injury or burns, certain cardiac disorders such as congestive heart failure. Treated concurrently or recently with agents or products that cause or increase the risk of hyperkalemia Avoid AMNEALYTE® in patients with, or at risk for hyperkalemia. If use cannot be avoided, monitor serum potassium concentrations. Although AMNEALYTE® has a potassium concentration in plasma, it is insufficient to produce a useful effect in case of severe potassium deficiency; therefore, it is not indicated for correction of severe potassium deficiency. PRECAUTIONS: In patients with renal impairment, administration of AMNEALYTE® may result in sodium and/or potassium or magnesium retention. AMNEALYTE® 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. Symptoms and treatment of overdosage: Excessive administration of AMNEALYTE® can cause: Fluid overload with a risk of edema (peripheral and/or pulmonary), particularly when renal sodium excretion is impaired. Hypernatremia and hyperkalemia, especially in patients with severe renal impairment. Hypermagnesemia. Metabolic alkalosis with or without hypokalemia and decreased ionized serum calcium and magnesium concentrations. When assessing an overdose, any additives in the solution must also be considered. The effects of an overdose may require immediate medical attention and treatment. Interventions include discontinuation of PAMNEALYTE®, dose reduction, and other measures as indicated for the specific clinical constellation (e.g., monitoring of fluid balance, electrolyte concentrations and acid base balance). Drug interaction: Avoid use of AMNEALYTE® in patients receiving such products, such as corticosteroids or corticotropin. If use cannot be avoided, monitor serum electrolytes, fluid balance and acid-base balance. Diuretics, and certain antiepileptic and psychotropic medications. Drugs that increase the vasopressin effect reduce renal electrolyte free water excretion and may also increase the risk of hyponatremia following treatment with intravenous fluids. potassium sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, or the immunosuppressants tacrolimus and cyclosporine. Drugs with pH Dependent Renal Elimination. dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Consider monitoring renal function in elderly patients. If use cannot be avoided, monitor the patient. Storage: Store at a temperature not exceeding 30°C. Discard Unused Portion. To be used with non-pyrogenic I.V. administration set with aseptic technique. Amneal Pharmaceuticals Private Limited

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