FIRST TIME GENERIC APPROVAL

Brand Name	Plasma-Lyte 148
Generic Name	multiple electrolytes Injection Type 1, USP, pH 5.5
Drug Manufacturer	Fresenius Kabi USA, LLC

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

June 29, 2022

LAUNCH DATE

June 13, 2023

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 215370

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Multiple Electrolytes Injection, Type 1, USP, pH 5.5 indicated as a source of water and electrolytes or as an alkalinizing agent.

MECHANISMS OF ACTION

N/A

DOSE FORM AND STRENGTH

Multiple Electrolytes Injection, Type 1, USP pH 5.5 500 mL x 20.

DOSE & ADMINISTRATION

Important Administration Instructions

- Multiple Electrolytes Injection, Type 1, USP, pH 5.5 is intended for intravenous (IV) 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 IV administration set to prevent air embolism.
- Use a dedicated line without any connections to avoid air embolism.

- Do not pressurize IV 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 the solution is clear, and container is undamaged.
- Multiple Electrolytes Injection, Type 1, USP, pH 5.5 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. Multiple Electrolytes Injection, Type 1, USP, pH 5.5 and 0.9% Sodium Chloride Injection, USP 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.