ALFA LABORATORIES S.A.L.

Peritoneal Dialysis Solution

Description:

Peritoneal dialysis solutions are sterile, nonpyrogenic solutions for intraperitoneal administration only. They contain no bacteriostatic or antimicrobial agents or added buffers.

Composition, calculated osmolarity, pH and ionic concentrations are shown below.

Composition/100mL

	Dextrose Hydrous USP	Sodium Chloride USP (NaCl)	Sodium Lactate (C3H5NaO3)	Calcium Chloride, USP (CaCl2•2H2O)	Magnesium Chloride, USP (MgCl2•6H2O)	Potassium Chloride USP	Osmolarity (mOsmol/L)	pH
Peritoneal Dialysis Solution with 1.5% Dextrose	1.5 g	567 mg	392 mg	25.7 mg	15.3 mg	0	347	5.0 to 6.5
Peritoneal Dialysis Solution with 4.25% Dextrose	4.25 g	567 mg	392 mg	25.7 mg	15.3 mg	0	486	5.0 to 6.5
Peritoneal Dialysis Solution (A formula)	1.36 g	560 mg	500 mg	26 mg	15 mg	30 mg	372	5.0 to 6.5

Ionic Concentration (mEq/L)

	Sodium	Calcium	Magnesium	Chloride	Lactate	Potassium
Peritoneal Dialysis Solution with 1.5%	132	3.5	1.5	102	35	0
Peritoneal Dialysis Solution with 4.5%	132	3.5	1.5	102	35	0
Peritoneal Dialysis Solution (A Formula)	140.44	3.537	1.475	104.86	44.618	4.024

Potassium is omitted from these Peritoneal Dialysis Solutions because dialysis may be performed to correct hyperkalemia. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) as in our **Peritoneal Dialysis Solution (A Formula)** may be indicated to prevent severe hypokalemia. Addition of potassium chloride should be made after careful evaluation of serum

and total body potassium and only under the direction of a physician. Frequent monitoring of serum electrolytes is indicated.

Clinical Pharmacology:

Peritoneal dialysis is a procedure for removing toxic substances and metabolites normally excreted by the kidneys, and for aiding in the regulation of fluid and electrolyte balance.

The procedure is accomplished by instilling peritoneal dialysis fluid through a conduit into the peritoneal cavity. With the exception of lactate, present as a bicarbonate precursor, electrolyte concentrations in the fluid have been formulated in an attempt to normalize plasma electrolyte concentrations resulting from osmosis and diffusion across the peritoneal membrane (between the patient's plasma and the dialysis fluid). Toxic substances and metabolites, present in high concentrations in the blood, cross the peritoneal membrane into the dialyzing fluid. Dextrose in the dialyzing fluid is used to produce a solution **hyperosmolar** to the plasma, creating an osmotic gradient which facilitates fluid removal from the patient's plasma into the peritoneal cavity. After a period of time (dwell time), the fluid is drained from the cavity.

Indications and Usage:

Peritoneal dialysis solutions are indicated for use in chronic renal failure patients being maintained on peritoneal dialysis.

Note: Not for use in the treatment of lactic acidosis.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over or under hydration with severe consequences including congestive heart failure, volume depletion, and shock.

Excessive use of Peritoneal Dialysis Solution with 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

When assessing peritoneal dialysis as the mode of therapy in extreme situations such as disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, fecal fistula or colostomy, tense ascites, obesity, and large polycystic kidneys, recent aortic graft replacement and severe pulmonary disease, the benefits to the patient must be weighed against the possible complications.

Significant losses of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided if necessary.

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Dosage and Administration:

Peritoneal Dialysis Solutions are intended for intraperitoneal administration only.

The mode of therapy (Intermittent Peritoneal Dialysis [IPD], Continuous Ambulatory Peritoneal Dialysis [CAPD], or Continuous Cyclic Peritoneal Dialysis [CCPD]), frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for and supervising the treatment of the individual patient.

To avoid the risk of severe dehydration and hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with the lowest level of osmolarity consistent with the fluid removal requirements for that exchange.

Peritoneal dialysis solutions may be warmed in the overpouch to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad) should be used. Solutions should not be heated in water due to an increased risk of infection. Microwave ovens should not be used to heat solutions because there is a potential for damage to the solution container. Moreover, microwave oven heating may potentially cause overheating and/or non-uniform heating of the solution that may result in patient injury or discomfort.

The addition of heparin to the dialysis solution may be indicated to aid in prevention of catheter blockage in patients with peritonitis, or when the solution drainage contains fibrinous or proteinaceous material.

Storage Conditions:

Store in moisture barrier overwrap between 4°C and 25°C until ready to use.

Packaging and Volumes:

DESCRIPTION			CODE		SHELF LIFE	PACKAGING (Bags)
PERITONEAL DIALYSIS SOLUTION WITH 1 1/2 % DEXTROSE	VIAFLEX BAG	2 LITERS	20	452-31	2 YEARS	6
PERITONEAL DIALYSIS SOLUTION (A FORMULA)	VIAFLEX BAG	3 LITERS	20	453-52	2 YEARS	4
PERITONEAL DIALYSIS SOLUTION WITH 4 1/4 % DEXTROSE	VIAFLEX BAG	2 LITERS	20	455-31	2 YEARS	6