ALFA LABORATORIES S.A.L.

20 % Mannitol Injection USP

Description:

20% Mannitol Injection USP is a hypertonic, sterile, nonpyrogenic solution of Mannitol USP in a single dose container for intravenous administration. It contains no antimicrobial agents. Mannitol is a 6-carbon sugar alcohol prepared commercially by the reduction of dextrose. Although virtually inert metabolically in humans, it occurs naturally in fruits and vegetables. Mannitol is an obligatory osmotic diuretic.

pH : 4.5 – 7.
Osmolarity: 1098 mOsmol/L.
Note: Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage. Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.

Clinical Pharmacology:

Mannitol Injection USP is one of the nonelectrolyte, obligatory, osmotic diuretics. It is freely filterable at the renal glomerulus, only poorly reabsorbed by the renal tubule, not secreted by the tubule, and is pharmacologically inert.

Mannitol, when administered intravenously, exerts its osmotic effect as a solute of relatively small molecular size being largely confined to the extracellular space. Only relatively small amounts of the dose administered are metabolized. Mannitol is readily diffused through the glomerulus of the kidney over a wide range of normal and impaired kidney function. In this fashion, approximately 80% of a 100 gram dose of mannitol will appear in the urine in three hours with lesser amounts thereafter. Even at peak concentrations, mannitol will exhibit less than 10% of tubular reabsorption and is not secreted by tubular cells. Mannitol will hinder tubular reabsorption of water and enhance excretion of sodium and chloride by elevating the osmolarity of the glomerular filtrate.

This increase in extracellular osmolarity effected by the intravenous administration of mannitol will induce the movement of intracellular water to the extracellular and vascular spaces. This action underlies the role of mannitol in reducing intracranial pressure, intracranial edema, and elevated intraocular pressure.

Indications and Usage:

20% Mannitol Injection USP is indicated for:

- Promotion of diuresis, in the prevention and/or treatment of the oliguric phase of acute renal failure before irreversible renal failure becomes established.
- Reduction of intracranial pressure and treatment of cerebral edema by reducing brain mass.
- Reduction of elevated intraocular pressure when the pressure cannot be lowered by other means.
- Promotion of urinary excretion of toxins.

Note : 20% mannitol Injection USP can be used as an osmotic diuretic in dogs.

20% Mannitol Injection USP is contraindicated in patients with:

- Well-established anuria due to severe renal disease.
- Severe pulmonary congestion or frank pulmonary edema.
- Active intracranial bleeding except during craniotomy.
- Severe dehydration.
- Progressive renal damage or dysfunction after institution of mannitol therapy, including increasing oliguria and azotemia.
- Progressive heart failure or pulmonary congestion after institution of mannitol therapy.

Dosage and Administration:

This solution is for intravenous use only.

The total dosage, concentration, and rate of administration should be governed by the nature and severity of the condition being treated, and the patient's fluid requirement and urinary output. The adult dosage ranges from 50 to 200 g in a 24-hour period, but in most cases an adequate response will be achieved at a usual dosage of approximately 100 g/24 hours. The rate of administration is usually adjusted to maintain a urine flow of at least 30 to 50 mL/hour. Lower mannitol concentrations and solutions containing sodium chloride are useful in preventing dehydration and electrolyte depletion. This outline of administration and dosage is only a general guide to therapy.

Dosage requirements for patients 12 years of age and under have not been established. As with adults, dose is dependent on weight, clinical condition.

Note: The usual canine dosage administered intravenously is 1.5 - 2.0 g per Kg body weight given over a 30 minute period. This is approximately 3.4 - 4.5 mL/lb of body weight.

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Storage Conditions:

Store in moisture barrier overwrap between 20°C and 25°C until ready to use.

Solutions of mannitol may crystallize when exposed to low temperatures. Concentrations greater than 15% have a greater tendency to crystallization. Inspect for crystals prior to administration. If crystals are observed, the container should be warmed by appropriate means to not greater than 60°C, shaken, then cooled to body temperature before administering. If all crystals cannot be completely redissolved, the container must be rejected.

Packaging and Volumes:

DESCRIPTION			CODE		SHELF LIFE	PACKAGING (BAGS)
20% MANNITOL	VIAFLEX BAG	250 mL	20	421-25	2 YEARS	36
20% MANNITOL	VIAFLEX BAG	500 mL	20	421-27	2 YEARS	24
20 % MANNITOL	NON PVC BAG	500 mL	10	421-27	5 YEARS	18