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Intravenous Injections in Plastic Bags

I. Dextrose for Injection

5% Dextrose Injection.

II. Single Electrolyte for Injection

1. 0.45% Sodium Chloride Injection.
2. 0.9% Sodium Chloride Injection.

III. Single Electrolyte with Dextrose for Injection

1. 3.3% Dextrose and 0.3% Sodium Chloride Injection.
2. 4.3% Dextrose and 0.18% Sodium Chloride Injection.
3. 5% Dextrose and 0.33% Sodium Chloride Injection.
4. 5% Dextrose and 0.45% Sodium Chloride Injection.
5. 5% Dextrose and 0.9% Sodium Chloride Injection.
6. 0.224% (30 mEq/L) Potassium Chloride in 5% Dextrose Injection.

IV. Multiple Electrolytes with Dextrose for Injection

1. 0.15% (20 mEq/L) Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection.
2. 0.224% (30 mEq/L) Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection.
3. 0.224% (30 mEq/L) Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection.

V. Multiple Electrolytes for Injection

1. Lactated Ringer's Injection.

Description

Intravenous solutions are sterile, nonpyrogenic solutions for fluid and electrolytes replenishment and/or caloric supply in single dose bags for intravenous administration. They contain no antimicrobial agents. The composition, osmolarity, and pH values are shown in Table 1.

Table 1
Composition, Osmolarity, and Approximate pH Values

	COMPOSITION						
	Dextrose Monohydrate (g/L)	Sodium Chloride (g/L)	Sodium Lactate (g/L)	Potassium Chloride (g/L)	Calcium Chloride Dihydrate(g/L)	Osmolarity* (mOsm/L)	Approx. pH **Values
5% Dextrose Injection	50	0	0	0	0	252	4.0
0.45% Sodium Chloride Injection	0	4.5	0	0	0	154	5.0
0.9% Sodium Chloride Injection	0	9.0	0	0	0	308	5.0
3.3% Dextrose & 0.3% Sodium Chloride Injection	33	3.0	0	0	0	269	4.0
4.3% Dextrose & 0.18% Sodium Chloride Injection	43	1.8	0	0	0	279	4.0
5% Dextrose & 0.33% Sodium Chloride Injection	50	3.3	0	0	0	365	4.0
5% Dextrose & 0.45% Sodium Chloride Injection	50	4.5	0	0	0	406	4.0
5% Dextrose & 0.9% Sodium Chloride Injection	50	9.0	0	0	0	560	4.0
0.224% (30 mEq/L) Potassium Chloride in 5% Dextrose Injection	50	0	0	2.24	0	312	4.5
0.15% (20 mEq/L) Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection:	50	3.3	0	1.5	0	405	4.5
0.224% (30 mEq/L) Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection	50	2.0	0	2.24	0	381	4.5
0.224% (30 mEq/L) Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection	50	4.5	0	2.24	0	466	4.5
Lactated Ringer's Injection	0	6.0	3.1	0.3	0.2	273	6.5

* Normal physiologic isotonicity range is approximately 280-310 mOsm/L.
Administration of substantially hypotonic solutions may cause hemolysis, and administration of substantially hypertonic solutions may cause vein damage.
**Approx. pH values are USP for applicable solutions, corporate specification for non-USP solutions.

Approximate ionic concentrations (mEq/L) and calories per liter are shown in Table 2.

Table 2
Approximate Ionic Concentrations (mEq/L) and Calories per liter

	Ionic Concentration (mEq/L)					
	Sodium	Potassium	Calcium	Chloride	Lactate	Caloric content (Kcal/L)
5% Dextrose Injection	0	0	0	0	0	170
0.45% Sodium Chloride Injection	77	0	0	77	0	0
0.9% Sodium Chloride Injection	154	0	0	154	0	0
3.3% Dextrose & 0.3% Sodium Chloride Injection	52	0	0	52	0	113
4.3% Dextrose & 0.18% Sodium Chloride Injection	31	0	0	31	0	147
5% Dextrose & 0.33% Sodium Chloride Injection	56	0	0	56	0	170
5% Dextrose & 0.45% Sodium Chloride Injection	77	0	0	77	0	170
5% Dextrose & 0.9% Sodium Chloride Injection	154	0	0	154	0	170
0.224% (30 mEq/L) Potassium Chloride in 5% Dextrose Injection	0	30	0	30	0	170
0.15% (20 mEq/L) Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection	56	20	0	76	0	170
0.224% (30mEq/L) Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection	34	30	0	64	0	170
0.224% (30 mEq/L) Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection	77	30	0	107	0	170
Lactated Ringer's Injection	130	4	2.7	109	28	9

The Plastic bag is fabricated from a specially formulated polyvinyl chloride. The amount of water that can permeate from inside the bag into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic bag can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexy phthalats (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological test for plastic containers as well as by tissue culture toxicity studies.

Clinical Pharmacology
Intravenous solutions have value as a source of water, electrolytes and/or calories. They are capable of inducing diuresis depending on the clinical condition of the patient.

For caloric value of the various solutions see Table 2.

Solutions which are di-electrolytic or polyelectrolytic have value in maintaining or replenishing electrolytes. See also Table 2 for ionic concentrations.

Solutions containing lactate ion produce a metabolic alkalinizing effect. Lactate ions are metabolized in the liver to glycogen, and ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications
Intravenous solutions are indicated as a source of water, electrolytes and/or calories.

0.9% and 0.45% Sodium Chloride Injections are also indicated for use as priming solutions in hemodialysis procedures.

Lactated Ringer's Injection is also indicated as an alkalizing agent.

Contraindications
None known.

Warnings
General
Note: Dispensing without Doctor's prescription is prohibited.

The administration of Intravenous Injections can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Excessive administration of potassium-free solutions may result in significant hypokalemia.

In patients with diminished renal function, administration of solutions containing sodium or potassium ions may result in sodium or potassium retention.

Administration by central venous catheter should be used only by those familiar with this technique and its complications.

For Solutions Containing Dextrose
Solutions containing dextrose with low electrolyte concentration should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis.

For Solutions Containing Sodium Ions
Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention. In patients with diminished renal function, administration of Sodium Chloride Injections may result in sodium retention.

For Solutions Containing Potassium Ions
Solutions containing potassium ions should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

For Solutions Containing Lactate Ions
Solutions containing lactate ions (especially Sodium Lactate Injection) should be used with great care, if at all, in patients with metabolic or respiratory alkalosis (excessive administration of Lactated Ringer’s Injection may result in metabolic alkalosis). The administration of lactate ions should be done with great care, in those conditions in which there is an increased level or an impaired utilization of lactate ions, such as severe hepatic insufficiency.

Lactated Ringer's Injection is not for use in the treatment of lactic acidosis.

For Solutions Containing Calcium Ions
Solutions containing calcium ions should not be administered simultaneously through the same administration set as blood because of the likelihood of coagulation.

Use in Pregnancy
Animal reproduction studies have not been conducted. It is also not known whether these solutions can cause fetal harm when administered to a pregnant woman, or can affect reproduction capacity. Therefore, these solutions should be given to a pregnant woman only if clearly needed.

Use in Pediatrics
For Solutions Containing Dextrose

These products should be used with caution in infants of diabetic mothers, except as may be indicated in hypoglycemic neonates.

Use in Pediatrics- for Lactated Ringer's Solution
Safety and effectiveness of Lactated Ringer's Injection in pediatric patients have not been established by adequate and well controlled trials; however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Use in Geriatrics - for Lactated Ringer's Solution
Clinical studies of Lactated Ringer's Injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, 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 drug therapy.

Adverse Reactions

General
Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

Nausea, fever, and flushing of the skin have occurred.

If an adverse reaction does occur, the infusions should be discontinued, the patient evaluated, appropriate therapeutic countermeasures instituted, and the remainder of the fluid saved for examination if deemed necessary.

For Lactated Ringer's Solution
Allergic reactions or anaphylactoid symptoms such as localized or generalized urticaria and pruritis; periorbital, facial, and/or laryngeal edema; coughing, sneezing, and/or difficulty with breathing have been reported during administration of Lactated Ringer's Injection. The reporting frequency of these signs and symptoms is higher in women during pregnancy.

Precautions

General

Do not administer unless the solution is clear and the seal is intact.

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy, or whenever the condition of the patient warrants such evaluation.

Caution should be exercised in the administration of parenteral fluids, especially those containing dextrose, sodium ions, to patients receiving corticosteroids or corticotropin.

Caution should be exercised in the administration of these injections to the very young and to elderly patients.

Administer so that extravasation does not occur. If thrombosis occurs during administration, stop injection and correct.

For Solutions Containing Dextrose

Solutions containing dextrose should be used with caution in patients with overt or subclinical diabetes mellitus, or carbohydrate intolerance.

Hyperglycemia and glycosuria may be functions of rate of administration or metabolic insufficiency. To minimize these conditions, slow the infusion rate, monitor blood and urine glucose; if necessary, administer insulin.

Vitamin B-complex deficiency may occur with dextrose administration.

Dosage and Administration

Note: Do not administer unless solution is clear and seal is intact.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions, where possible.

The dosage is usually dependent upon the age, weight and clinical condition of the patient, as well as laboratory determinations. All injections in plastic bags are intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Additives may be incompatible Complete information is not available. Those additives known to be incompatible should not be used. A pharmacist should be consulted, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, aseptic technique should be used. Thorough mixing should be performed when additives have been introduced. *Solutions containing additives must not be stored.*

Directions for Use of Plastic Bags

Warning : Do not use plastic bags in series connections. Such use could result in air embolism due to residual air being drawn from the primary bag before administration of the fluid from the secondary bag is completed.

To Open

Do not remove units from overwrap until ready for use. Use all units promptly when pouch is opened.

The overwrap is a moisture barrier. The inner bag maintains the sterility of the product.

Tear pouch down side at slit and remove solution bag. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administration.

Preparation for Administration

1. Suspend bag from eyelet support.
2. Remove plastic protector from outlet port at bottom of bag.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication Before Solution Administration

***Warning*:** Additives may be incompatible.

1. Prepare medication site.
2. Using syringe with 19-22 gauge needle, puncture medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To Add Medication During Solution Administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19-22 gauge needle, puncture resealable medication port and inject.
4. Remove bag from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while bag is in the upright position.
6. Mix solution and medication thoroughly.
7. Return bag to in use position and continue administration.

Overdosage

In the event of fluid or solute overload during parenteral fluids, reevaluate the patient's condition and institute appropriate corrective treatment.

Storage

Avoid storage at excessive heat. It is recommended that the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Registration Numbers

5% Dextrose Injection	015 37 24548 00
0.9% Sodium Chloride Injection	015 89 2 4546 00
0.45% Sodium Chloride Injection	041 21 23285.00
3.3% Dextrose and 0.3% Sodium Chloride Injection	015 50 24550 00
4.3% Dextrose and 0.18% Sodium Chloride Injection	031 86 21886.00
5% Dextrose and 0.33% Sodium Chloride Injection	042 61 22887 00
5% Dextrose and 0.45% Sodium Chloride Injection	038 88 22826.00
5% Dextrose and 0.9% Sodium Chloride Injection	019 09 20395 00
0.224% (30 mEq/L) Potassium Chloride in 5% Dextrose Injection	019 19 20786 00
0.15% (20 mEq/L) Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection	042 09 25939 00
0.224% (30 mEq/L) Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection	054 83 22828 00
0.224% (30 mEq/L) Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection	038 40 22827 00
Lactated Ringer's Injection	025 29 20064 00

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