PRESCRIBING INFORMATION

3.3% Dextrose and 0.3% Sodium Chloride Injection

5% Dextrose and 0.2% Sodium Chloride Injection

5% Dextrose and 0.45% Sodium Chloride Injection

5% Dextrose and 0.9% Sodium Chloride Injection

10% Dextrose and 0.9% Sodium Chloride Injection

Dextrose and Sodium Chloride Injection, USP

IV Fluid and Nutrient Replenisher

In VIAFLEX Plastic Container

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Dextrose and Sodium Chloride Injection, USP

In VIAFLEX Plastic Container

SUMMARY PRODUCT INFORMATION

Dextrose and Sodium Chloride Injection USP solutions are sterile, nonpyrogenic and contain no bacteriostatic or antimicrobial agents or added buffers. The composition, osmolarity and approx. pH of the individual solutions are shown in Table 1.

Table 1.

	Size (mL)	DIN	Composition (g/L)		Osmolarity (mOsmol/L)	pH	Ionic Concentration (mmol/L)		Caloric Content (cal/L)
			*Dextrose Monohyd.	Sodium Chloride			Sodium	Chloride	
3.3% Dextrose & 0.3% NaCl	250	00060712	33.0 g	3.0 g	269	3.5 to 6.5	51	51	112
	500								
	1000								
5% Dextrose & 0.2% NaCl	250	00060704	50.0 g	2.0 g	321	3.5 to 6.5	34	34	170
	500								
	1000								
5% Dextrose & 0.45% NaCl	500	00060739	50.0 g	4.5 g	406	3.5 to 6.5	77	77	170
	1000								
5% Dextrose & 0.9% NaCl	250	00060747	50.0 g	9.0 g	560	3.5 to 6.5	154	154	170
	500								
	1000								
10% Dextrose & 0.9% NaCl	1000	00060755	100.0 g	9.0 g	813	3.5 to 6.5	154	154	340

*The dextrose is purified from corn and may contain fructose.

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic).

Water in a solution in the container can permeate through the plastic wall, but in an insufficient amount to significantly affect the solution. Before the product expires, a very small amounts of chemical components of the plastic can be leached into the solution in the container, such as up to 5 parts per million for di-2-ethylhexyl phthalate (DEHP). No safety issues of the plastic material were identified in USP biological tests in animals as well as by tissue culture toxicity studies.

ACTIONS

Dextrose and Sodium Chloride Injection USP solutions are a source of water for hydration and provide electrolytes and calories. Dextrose and Sodium Chloride Injection USP solutions are capable of inducing diuresis depending on the clinical conditions of the patient. See Table 1 for calories per liter of the various solutions.

Solutions which are di-electrolytic or polyelectrolytic have value in maintaining or replenishing electrolytes. See Table 1 for ionic concentrations.

INDICATIONS AND CLINICAL USE

Dextrose and Sodium Chloride Injection USP solutions are indicated as a supply of water or for administration of electrolytes or calories.

CONTRAINDICATIONS

Dextrose and Sodium Chloride Injection, USP is contraindicated in the following conditions:

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the SUMMARY PRODUCT INFORMATION section of the Prescribing Information.
- Known allergy to corn or corn products since dextrose in the products is purified from corn.
- Clinically significant hyperglycemia

WARNINGS AND PRECAUTIONS

General

Normal physiologic isotonicity range is approximately 280-310 mOsmol/liter. Administration of substantially hypotonic solutions may cause hemolysis and administration of substantially hypertonic solutions may cause vein damage.

Dextrose and Sodium Chloride Injection USP solutions 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.

The intravenous administration of Dextrose and Sodium Chloride Injection USP solutions 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 solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the solutions.

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

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

Hypersensitivity Reactions

Hypersensitivity/infusion reactions, including anaphylaxis, have been reported with Dextrose and Sodium Chloride Injection USP solutions (see Adverse Reactions).

The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity/infusion reaction develop.

Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Since the dextrose in Dextrose and Sodium Chloride Injection USP solutions is derived from corn, the product should not be used in patients with known allergy to corn or corn products (see CONTRAINDICATIONS section).

Hyponatremia

The infusion of solutions with sodium concentrations <0.9% may result in hyponatremia.

Close clinical monitoring may be warranted.

Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema, and death. Acute symptomatic hyponatremic encephalopathy is considered a medical emergency.

Dextrose and Sodium Chloride Injection USP solutions should be used with particular caution, in patients with or at risk for hyponatremia is increased, for example,

- in children
- in elderly patients
- in women
- postoperatively
- in persons with psychogenic polydipsia
- in patients treated with medications that increase the risk of hyponatremia (such as certain antiepileptic and psychotropic medications).

The risk for developing hyponatremic encephalopathy is increased, for example,

- in pediatric patients (≤16 years of age)
- in women (in particular, premenopausal women)
- in patients with hypoxemia
- in patients with underlying central nervous system disease.

Use in patients at risk for sodium retention, fluid overload and edema

Dextrose and Sodium Chloride Injection USP solutions should be used with particular caution, in patients with or at risk for:

- Hypernatremia (applies to solutions containing 0.9% sodium chloride)
- Hyperchloremia (applies to solutions containing 0.9% sodium chloride)
- Metabolic acidosis (applies to solutions containing 0.9% sodium chloride)
- Hypervolemia
- Conditions that may cause sodium retention, fluid overload and edema (central and peripheral)

Medications that may increase the risk of sodium and fluid retention, such as corticosteroids.

Hypokalemia

The infusion of Dextrose and Sodium Chloride Injection USP solutions may result in hypokalemia.

Dextrose and Sodium Chloride Injection USP solutions should be used with particular caution in patients with or at risk for hypokalemia, close clinical monitoring may be warranted, for example:

- in persons with metabolic alkalosis
- in persons with thyrotoxic periodic paralysis, administration of intravenous dextrose has been associated in aggravating hypokalemia
- in persons with increased gastrointestinal losses (e.g. diarrhea, vomiting)
- prolonged low potassium diet
- in persons with primary hyperaldosteronism

in patients treated with medications that increase the risk of hypokalemia (e.g. diuretics, beta-2 agonist, or insulin)

Dilution and other effects on serum electrolytes and water imbalance

Depending on the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize dextrose, intravenous administration of Dextrose and Sodium Chloride Injection USP solutions can cause:

- Hyperosmolality, osmotic diuresis and dehydration
- Hypoosmolality
- Electrolyte disturbances such as
  - Hyponatremia,
  - Hypokalemia,
  - Hypophosphatemia,
  - Hypomagnesemia,
- Overhydration/hypervolemia and, for example, congested states, including central (e.g. pulmonary congestion) and peripheral edema.
- Acid-base imbalance (applies to solutions containing 0.9% sodium chloride)
- An increase in serum glucose concentration is associated with an increase in serum osmolality. Osmotic diuresis associated with hyperglycemia can result in or contribute to the development of dehydration and in electrolyte losses. (applies to solutions containing 0.9% sodium chloride)

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

Hyperglycemia

Rapid administration of dextrose solutions may produce substantial hyperglycemia and hyperosmolar syndrome.

In order to avoid hyperglycemia the infusion rate should not exceed the patient's ability to utilize glucose.

To reduce the risk of hyperglycemia-associated complications, the infusion rate must be adjusted and/or insulin administered if blood glucose levels exceed levels considered acceptable for the individual patient.

Intravenous dextrose should be administered with caution in patients with, for example:

- impaired glucose tolerance (such as in diabetes mellitus, renal impairment, or in the presence of sepsis, trauma, or shock),
- severe malnutrition (risk of precipitating a refeeding syndrome),
- thiamine deficiency, e.g., in patients with chronic alcoholism (risk of severe lactic acidosis due to impaired oxidative metabolism of pyruvate),
- water and electrolyte disturbances that could be aggravated by increased glucose and/or free water load

Other groups of patients in whom Dextrose and Sodium Chloride Injection USP solutions should be used with caution include:

- patients with ischemic stroke. hyperglycemia has been implicated in increasing cerebral ischemic brain damage and impairing recovery after acute ischemic strokes.
- patients with severe traumatic brain injury (in particular during the first 24 hours following the trauma). Early hyperglycemia has been associated with poor outcomes in patients with severe traumatic brain injury.
- Newborns (See Pediatric glycemia-related issues).

Prolonged intravenous administration of dextrose and associated hyperglycemia may result in decreased rates of glucose-stimulated insulin secretion.

Refeeding Syndrome

Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications.

Use in Patients with or at risk of Severe Renal Impairment

Dextrose and Sodium Chloride Injection USP solutions should be administered with particular caution, to patients with or at risk of (severe) renal impairment. In such patients, administration of Dextrose and Sodium Chloride Injection USP solutions may result in sodium retention and/or fluid overload.

Blood

Dextrose and Sodium Chloride Injection USP solutions should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination (for solutions with Dextrose more or equal to 5%) or hemolysis.

Risk of Air Embolism

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container.
Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

SPECIAL POPULATIONS

Pregnancy and Lactation

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

Intrapartum maternal intravenous dextrose infusion may result in fetal hyperglycemia and metabolic acidosis as well as rebound neonatal hypoglycemia due to fetal insulin production.

Healthcare practitioners should carefully consider the potential risks and benefits for each specific patient before administering Dextrose and Sodium Chloride Injection, USP solutions.

Pediatrics

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in pediatric intravenous fluid therapy Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes.

The infusion of hypotonic fluids (applies to solutions containing less than 0.9% sodium chloride) together with the non-osmotic secretion of Antidiuretic hormone (ADH) may result in hyponatremia. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death, therefore acute symptomatic hyponatremic encephalopathy is considered a medical emergency (applies to solutions containing less than 0.9% sodium chloride).

Pediatric Glycemia-related Issues

Newborns – especially those born premature and with low birth weight - are at increased risk of developing hypo- or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycemic control in order to avoid potential long term adverse effects.

Hypoglycemia in the newborn can cause, e.g.,

- prolonged seizures,
- coma, and
- cerebral injury, including brain damage.

Hyperglycemia has been associated with

- cerebral injury, including intraventricular hemorrhage,
- late onset bacterial and fungal infection,
- retinopathy of prematurity,
- necrotizing enterocolitits,
- increased oxygen requirements ,
- prolonged length of hospital stay, and
- death.

Pediatric Hyponatremia-related Issues

Children (including neonates and older children) are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy.

The infusion of hypotonic fluids together with the non-osmotic secretion of ADH may result in hyponatremia.

Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death; therefore, acute symptomatic hyponatremic encephalopathy is considered a medical emergency.

Plasma electrolyte concentrations should be closely monitored in the pediatric population.

Rapid correction of hyponatremia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a physician experienced in pediatric intravenous fluid therapy.

Geriatrics

When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases or concomitant drug therapy. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range.

ADVERSE REACTIONS

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.

If any adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasure, and save the remainder of the fluid and administration set for examination if deemed necessary.

Post-Marketing Adverse Reactions

The following adverse reactions have been reported in post-marketing experience:
IMMUNE SYSTEM DISORDERS: Anaphylactic reaction, Hypersensitivity

METABOLISM AND NUTRITION DISORDERS: Hyponatremia (applies to solutions containing less than 0.9% sodium chloride), Hypernatremia (applies to solutions containing 0.9% sodium chloride), Hyperglycemia

VASCULAR DISORDERS: Phlebitis

SKIN AND SUBCUTANEOUS TISSUE DISORDERS: Rash, Pruritus

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: Injection site reactions including: Infusion site pain, Injection site vesicles, chills, pyrexia

DRUG INTERACTIONS

Both the glycemic effects of Dextrose and Sodium Chloride Injection USP solutions and its effects on water and electrolyte balance should be taken into account when using Dextrose and Sodium Chloride Injection USP solutions in patients treated with other substances that affect glycemic control, or fluid and/or electrolyte balance.

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased during administration of Dextrose and Sodium Chloride Injection USP solutions and can result in decreased lithium levels.

DOSAGE AND ADMINISTRATION

As directed by a physician.The choice of the specific sodium chloride and dextrose concentrations, dosage, volume, rate and duration of administration depend on the age, weight and clinical condition of the patient and concomitant therapy, and administration should be determined by a physician. For patients with electrolyte and glucose abnormalities and for pediatric patients, consult a physician experienced in intravenous fluid therapy.All Dextrose and Sodium Chloride Injections in VIAFLEX plastic containers are intended for intravenous infusion using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Use of an in-line filter is recommended during administration of all parenteral solutions where possible.

Hyperosmolar solutions may cause venous irritation and phlebitis. Thus, any hyperosmolar solutions are recommended to be administered through a large central vein, for rapid dilution of the hypertonic solution. See Table 1 for information on the products' osmolarity.

The osmolarity of a final admixed solution must be taken into account when peripheral administration is considered.

Rapid correction of hyponatremia and hypernatremia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a physician experienced in intravenous fluid therapy.

A gradual increase of flow rate should be considered when starting administration of dextrose-containing products.

Electrolyte supplementation may be indicated according to the clinical needs of the patient.

Additives may be incompatible. Compatibility of additives must be checked before adding medication. Those additives known to be incompatible should not be used. When introducing additives to Dextrose and Sodium Chloride Injection USP solutions, the instructions for use of the medication to be added and other relevant literature must be consulted.

If in the informed judgment of the physician it is deemed advisable to introduce additives, use aseptic technique.

Before adding a substance or medication, verify that it is soluble in and/or stable in Dextrose and Sodium Chloride Injection USP solutions and that the pH range of Dextrose and Sodium Chloride Injection USP solutions is appropriate.

After addition, check for a possible color change and/or the appearance of precipitates, insoluble complexes or crystals.

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

Thorough and careful mixing of any additive is mandatory. Do not store solutions containing additives.

For single use only.

Discard any unused portion.

OVERDOSAGE

Excess administration of Dextrose and Sodium Chloride Injection USP solutions can cause:

- hyperglycemia, adverse effects on water and electrolyte balance, and corresponding complications. For example, severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal.

- hyponatremia (which can lead to CNS manifestations, including seizures, coma, cerebral edema and death).
- hypernatremia especially in patients with severe renal impairment (applies to solutions containing 0.9% sodium chloride).
- Fluid overload (which can lead to central and/or peripheral edema).
- See also WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS sections

When assessing an overdose, any additives in the solution must also be considered.

Clinically significant overdose of Dextrose and Sodium Chloride Injection USP solutions may, therefore, constitute a medical emergency.

Interventions include discontinuation of Dextrose and Sodium Chloride Injection USP solutions administration, dose reduction, administration of insulin and other measures as indicated for the specific clinical constellation.

DOSAGE FORMS, COMPOSITION AND PACKAGING

How Supplied

Table 1 shows the composition, osmolarity, approx pH, and ionic concentration of Dextrose and Sodium Chloride Injections.

Dextrose and Sodium Chloride Injection products are packaged in the Viaflex plastic container which is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic).

The available package sizes of Dextrose and Sodium Chloride Injection products are listed in Table 2.

Table 2. Package sizes of Dextrose and Sodium Chloride Injection products

Product	Package size
3.3% Dextrose and 0.3% Sodium Chloride Injection	500mL, 1000mL
5% Dextrose and 0.2% Sodium Chloride Injection	500mL
5% Dextrose and 0.45% Sodium Chloride Injection	500mL, 1000mL
5% Dextrose and 0.9% Sodium Chloride Injection	500mL, 1000mL
10% Dextrose and 0.9% Sodium Chloride Injection	1000mL

Directions for use of VIAFLEX Plastic Container

WARNING: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air (approximately 15 mL) being drawn from the primary container before administration of the fluid from the secondary container is completed.

Do not remove unit from overwrap until ready to use.

To Open

Tear overwrap down side at slit and remove solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administration. Some opacity of the plastic due to moisture absorption during sterilization process may be observed. This is normal and does not affect the solution quality and safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found discard solution as sterility may be impaired.

Preparation for Administration

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

To Add Medication

1. Prepare medication site.
2. Using a syringe and 20 - 22 gauge needle, puncture resealable rubber plug at target area and inject. Multiple additions may be made in this manner.
3. Mix solution and medication thoroughly. For high density medications such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

Storage

Store at 15°C to 25°C

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