HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DEXTROSE AND SODIUM CHLORIDE INJECTION safely and effectively. See full prescribing information for DEXTROSE AND SODIUM CHLORIDE INJECTION.

DEXTROSE AND SODIUM CHLORIDE injection, for intravenous use
Initial U.S. Approval: 1970

----------RECENT MAJOR CHANGES----------

Dosage and Administration (2.1, 2.2, 2.3)	09/2026
Contraindications (4)	09/2026
Warnings and Precautions (5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9)	09/2026

----------INDICATIONS AND USAGE----------
Dextrose and Sodium Chloride Injection is indicated as a source of water, electrolytes, and calories in adults and pediatric patients. (1)

----------DOSAGE AND ADMINISTRATION----------
- Only for intravenous infusion. (2.1)
- Infusion rate depends on the age, weight, clinical, and metabolic conditions of the patient and concomitant therapy. See full prescribing information for more information on preparation, administration, and dosing considerations. (2.1, 2.2, 2.3)

----------DOSAGE FORMS AND STRENGTHS----------
Injection: Dextrose hydrous and sodium chloride in clear, sterile, and nonpyrogenic solutions, available in single-dose EXCEL® flexible containers (250 mL, 500 mL and 1000 mL) in the following concentrations: (3)
- 3.3% (3.3 g/100 mL) (33 mg/mL) Dextrose and 0.3% (0.3 g/100 mL) (3 mg/mL) Sodium Chloride Injection
- 5% (5 g/100 mL) (50 mg/mL) Dextrose and 0.9% (0.9 g/100 mL) (9 mg/mL) Sodium Chloride Injection
- 5% (5 g/100 mL) (50 mg/mL) Dextrose and 0.45% (0.45 g/100 mL) (4.5 mg/mL) Sodium Chloride Injection
- 5% (5 g/100 mL) (50 mg/mL) Dextrose and 0.33% (0.33 g/100 mL) (3.3 mg/mL) Sodium Chloride Injection
- 5% (5 g/100 mL) (50 mg/mL) Dextrose and 0.2% (0.2 g/100 mL) (2 mg/mL) Sodium Chloride Injection
- 10% (10 g/100 mL) (100 mg/mL) Dextrose and 0.45% (0.45 g/100 mL) (4.5 mg/mL) Sodium Chloride Injection
- 10% (10 g/100 mL) (100 mg/mL) Dextrose and 0.2% (0.2 g/100 mL) (2 mg/mL) Sodium Chloride Injection

----------CONTRAINDICATIONS----------
- Known hypersensitivity to dextrose or sodium chloride (4)
- Clinically significant hyperglycemia (4)

----------WARNINGS AND PRECAUTIONS----------
- Neonatal Hypoglycemia: Closely monitor blood glucose concentration to ensure adequate glycemic control. (5.1)
- Hypersensitivity Reactions: Monitor for signs and symptoms and discontinue infusion immediately if reaction occurs. (5.2)
- Hyperglycemia and Hyperosmolar Hyperglycemic State: Use with caution in patients with known subclinical or overt diabetes mellitus. (5.3)
- Hyponatremia, Hypokalemia, Hypernatremia and Hyperchloremia: Avoid in patients with or at risk for hypo-/hypernatremia and hypokalemia. If use cannot be avoided, monitor serum sodium and potassium concentrations. (5.4, 5.5, 5.6)
- Fluid Overload: Avoid in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor daily fluid balance and electrolyte concentrations and acid-base balance, as needed and especially during prolonged use. (5.7)
- Phlebitis and Thrombosis: Remove catheter as soon as possible if thrombophlebitis develops. (5.8)
- Refeeding Syndrome: Monitor severely undernourished patients and slowly increase nutrient intake. (5.9)

----------ADVERSE REACTIONS----------
The most common adverse reactions include electrolyte imbalances, hyperglycemia, and hypervolemia, and injection site reactions. (6)

To report SUSPECTED ADVERSE REACTIONS, contact B. Braun Medical Inc. at 1-833-425-1464 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Effects on Glycemic Control, Vasopressin, Fluid, and Electrolyte Balance: Monitor blood glucose concentrations, fluid balance, serum electrolyte concentrations, and acid-base balance. (7.1)
- Lithium: Monitor serum lithium concentrations during concomitant use. (7.2)

Revised: 09/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

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*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Dextrose and Sodium Chloride Injection is indicated as a source of water, electrolytes, and calories in adults and pediatric patients.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

- Dextrose and Sodium Chloride Injection is intended for intravenous use.
- Use a peripheral vein to administer if the final dextrose concentration is 5% or less and the osmolarity is less than 900 mOsm/L.
- Consider using a central vein to administer hypertonic solutions with osmolarity of 900 mOsm/L or greater to avoid venous irritation *[see Warnings and Precautions (5.8)]*.
- Avoid administering Dextrose and Sodium Chloride Injection simultaneously with blood products through the same administration set because of the possibility of pseudoagglutination or hemolysis. If there is only a single IV access, flush the line thoroughly with normal saline before and after blood product administration.
- Use of a final filter is recommended during administration of parenteral solutions, where possible.
- Discard the unused portion.

2.2 Important Preparation Information

Visually inspect the Dextrose and Sodium Chloride Injection for particulate matter and discoloration. Do not administer Dextrose and Sodium Chloride Injection if the solution is cloudy, there are precipitates, or the container is damaged.

To reduce the risk of air embolism, adhere to the following preparation instructions for Dextrose and Sodium Chloride Injection:

- Use a non-vented infusion set or close the vent on a vented set.
- Use a dedicated line without any connections (do not connect flexible containers in series). Do **not** pressurize the flexible container to increase flow rates.
- The use of pressure infusion is not recommended as a method to increase flow rates. However, if pressure infusion is required, ensure that any air within the bag is fully evacuated prior to initiation of infusion.
- If using a pumping device to administer Dextrose and Sodium Chloride Injection, turn off the pump before the container is empty.

<u>To Open EXCEL® Containers</u>

- Do not remove container from overwrap until ready to use.
- Tear overwrap down side at slit and remove solution container.

- Visually inspect the container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Evaluate the following:
    - If the outlet port protector is damaged, detached, or not present, discard container.
    - Check to ensure the solution is clear and there are no precipitates. Discard if there is a color change and/or the appearance of precipitates, insoluble complexes or crystals.
    - Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard container.

Preparation for Administration

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

To Add Medication

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

To Add Medication Before Solution Administration

1. Prepare medication site.
2. Using syringe with 18 to 22-gauge needle, puncture resealable 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.
4. After addition, check to ensure the solution is clear and there are no precipitates. Discard if there is a color change and/or the appearance of precipitates, insoluble complexes or crystals.

To Add Medication During Solution Administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 18 to 22-gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. After addition, check to ensure the solution is clear and there are no precipitates. Discard if there is a color change and/or the appearance of precipitates, insoluble complexes or crystals, do not use.
8. Return container to in use position and continue with administration.

2.3 Recommended Dosage

The choice of the specific, sodium chloride, and dextrose concentrations, rate and volume depends on the age, weight, clinical and metabolic conditions of the patient and concomitant therapy. Electrolyte supplementation may be indicated according to the clinical needs of the patient.

The administration rate should be governed, especially for preterm neonates with low birth weight, during the first few days of therapy, by the patient's tolerance to dextrose. Increase the infusion rate gradually as indicated by frequent monitoring of blood glucose concentrations *[see Warnings and Precautions (5.1), Use in Specific Populations (8.4)].*

3 DOSAGE FORMS AND STRENGTHS

Injection: Dextrose hydrous and sodium chloride in clear, sterile, and nonpyrogenic solutions, available in single-dose EXCEL® flexible containers (250 mL, 500 mL and 1000 mL) in the following concentrations:

- 3.3% (3.3 g/100 mL) (33 mg/mL) Dextrose and 0.3% (0.3 g/100 mL) (3 mg/mL) Sodium Chloride Injection, USP
- 5% (5 g/100 mL) (50 mg/mL) Dextrose and 0.9% (0.9 g/100 mL) (9 mg/mL) Sodium Chloride Injection, USP
- 5% (5 g/100 mL) (50 mg/mL) Dextrose and 0.45% (0.45 g/100 mL) (4.5 mg/mL) Sodium Chloride Injection, USP
- 5% (5 g/100 mL) (50 mg/mL) Dextrose and 0.33% (0.33 g/100 mL) (3.3 mg/mL) Sodium Chloride Injection, USP
- 5% (5 g/100 mL) (50 mg/mL) Dextrose and 0.2% (0.2 g/100 mL) (2 mg/mL) Sodium Chloride Injection, USP
- 10% (10 g/100 mL) (100 mg/mL) Dextrose and 0.45% (0.45 g/100 mL) (4.5 mg/mL) Sodium Chloride Injection, USP
- 10% (10 g/100 mL) (100 mg/mL) Dextrose and 0.2% (0.2 g/100 mL) (2 mg/mL) Sodium Chloride Injection, USP

4 CONTRAINDICATIONS

Dextrose and Sodium Chloride Injection is contraindicated in patients with:

- Known hypersensitivity to dextrose and/or sodium chloride *[see Warnings and Precautions (5.2)]*
- Clinically significant hyperglycemia *[see Warnings and Precautions (5.3)]*

5 WARNINGS AND PRECAUTIONS

5.1 Neonatal Hypoglycemia

Neonates, especially preterm neonates with low birth weight, are at increased risk of developing hypoglycemia. Closely monitor blood glucose concentration during treatment with Dextrose and Sodium Chloride Injection to ensure adequate glycemic control in order to avoid potential long-term adverse effects.

5.2 Hypersensitivity Reactions

Hypersensitivity and infusion reactions, including anaphylaxis, have been reported with Dextrose and Sodium Chloride Injection *[see Adverse Reactions (6)]*. Stop administration of Dextrose and Sodium Chloride Injection immediately if signs or symptoms of a hypersensitivity reaction develop. Initiate appropriate treatment as clinically indicated.

5.3 Hyperglycemia and Hyperosmolar Hyperglycemic State

The use of Dextrose and Sodium Chloride Injection in patients with impaired glucose tolerance may worsen hyperglycemia. Administration of dextrose at a rate exceeding the patient's utilization rate may lead to hyperglycemia, coma, and death.

Hyperglycemia is associated with an increase in serum osmolality, resulting in osmotic diuresis, dehydration and electrolyte losses *[see Warnings and Precautions (5.3, 5.4, 5.5), Use in Specific Populations (8.4)]*. Patients with underlying central nervous system disease and renal impairment who receive dextrose infusions, may be at greater risk of developing hyperosmolar hyperglycemic state.

Monitor blood glucose concentrations and treat hyperglycemia to maintain concentrations within normal limits while administering Dextrose and Sodium Chloride Injection. Insulin may be administered or adjusted to maintain optimal blood glucose concentrations during Dextrose and Sodium Chloride Injection administration.

5.4 Hyponatremia

Dextrose and Sodium Chloride Injection may cause hyponatremia. The risk of hospital-acquired hyponatremia is increased in younger pediatric patients, geriatric patients, patients treated with diuretics, and patients with cardiac or pulmonary failure or with the syndrome of inappropriate antidiuretic hormone (SIADH) (e.g., postoperative patients, patients concomitantly treated with arginine vasopressin analogs or certain antiepileptic, psychotropic, and cytotoxic drugs) *[see Drug Interactions (7.1), Use in Specific Populations (8.4)]*.

Rapid correction of hyponatremia is potentially dangerous with risk of serious neurologic complications such as osmotic demyelination syndrome (ODS) with risk of seizures and cerebral edema. To avoid complications, monitor serum sodium and chloride concentrations, fluid status, acid-based balance, and signs of neurologic complications.

Avoid Dextrose and Sodium Chloride Injection in patients with or at risk for hyponatremia. If use cannot be avoided, closely monitor serum sodium concentrations, chloride concentrations, fluid status, acid-base balance, and neurologic status *[see Warnings and Precautions (5.5, 5.6, 5.7)]*.

5.5 Hypokalemia

Excessive administration of Dextrose and Sodium Chloride Injection may result in significant hypokalemia. Hypokalemic periodic paralysis, metabolic alkalosis, increased gastrointestinal losses (e.g. diarrhea, vomiting), prolonged low potassium diet, or primary hyperaldosteronism may increase the risk of hypokalemia. Avoid the administration of Dextrose and Sodium Chloride Injection in patients with or at risk of hypokalemia or taking medications that may increase the risk. If use cannot be avoided, monitor serum potassium levels.

5.6 Hypernatremia and Hyperchloremia

Electrolyte imbalances such as hypernatremia and hyperchloremia, leading to metabolic acidosis may occur with solutions containing 0.9% sodium chloride.

Conditions that may increase the risk of hypernatremia, fluid overload, and edema (central and peripheral), include patients with pre-eclampsia, primary hyperaldosteronism and secondary hyperaldosteronism associated with, for example, hypertension, congestive heart failure, severe renal impairment, liver disease (including cirrhosis), and renal disease (including renal artery stenosis, nephrosclerosis).

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

Avoid solutions containing 0.9% sodium chloride in patients with or at risk for hypernatremia. If use cannot be avoided, monitor serum sodium concentrations.

5.7 Fluid Overload

Depending on the volume and rate of infusion, the patient's underlying clinical condition and capability to metabolize dextrose, intravenous administration of Dextrose and Sodium Chloride Injection can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

Avoid Dextrose and Sodium Chloride Injection in patients with or at risk for fluid and/or solute overload. If use cannot be avoided, monitor fluid balance, electrolyte concentrations, and acid-base balance, especially during prolonged use. Additional monitoring is recommended for patients with water and electrolyte disturbances that could be aggravated by increased glucose, insulin administration and/or free water load.

5.8 Phlebitis and Thrombosis

The infusion of hypertonic solutions into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis *[see Dosage and Administration (2.1)]*. If thrombophlebitis develops, remove the catheter as soon as possible.

5.9 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. To prevent these complications, monitor severely undernourished patients and slowly increase nutrient intake.

6 ADVERSE REACTIONS

- Neonatal Hypoglycemia *[see Warnings and Precautions (5.1)]*
- Hypersensitivity *[see Warnings and Precautions (5.2)]*
- Hyperglycemia and Hyperosmolar Hyperglycemic State *[see Warnings and Precautions (5.3)]*
- Hyponatremia *[see Warnings and Precautions (5.4)]*
- Hypokalemia *[see Warnings and Precautions (5.5)]*
- Hypernatremia and Hyperchloremia *[see Warnings and Precautions (5.6)]*
- Fluid Overload *[see Warnings and Precautions (5.7)]*
- Phlebitis and Thrombosis *[see Warnings and Precautions (5.8)]*
- Refeeding syndrome *[see Warnings and Precautions (5.9)]*

The following adverse reactions associated with the use of Dextrose and Sodium Chloride Injection were identified in clinical studies or postmarketing reports. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Administration site conditions:
Blister, erythema, extravasation, pain, phlebitis, vein damage, thrombosis.

Immune system disorders:
Anaphylaxis, angioedema, bronchospasm, chills, hypotension, pruritus, pyrexia, rash.

Cardiovascular disorders:
Cyanosis, volume overload.

7 DRUG INTERACTIONS

7.1 Effects on Glycemic Control, Vasopressin, Fluid, and Electrolyte Balance

Dextrose and Sodium Chloride Injection can affect glycemic control, vasopressin and fluid and/or electrolyte balance *[see Warnings and Precautions (5.3, 5.4, 5.5, 5.6, 5.7)].* Monitor patients' blood glucose concentrations, fluid balance, serum electrolyte concentrations, and acid-base balance.

Concomitant administration of Dextrose and Sodium Chloride Injection with drugs associated with hyponatremia may increase the risk of developing hyponatremia. Drugs associated with hyponatremia include diuretics and those that cause SIADH (e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), arginine vasopressin analogs, certain antiepileptic, psychotropic, and cytotoxic drugs).

Avoid use of Dextrose and Sodium Chloride Injection in patients receiving drugs associated with hyponatremia. If use cannot be avoided, closely monitor serum sodium concentrations during concomitant use *[see Warnings and Precautions (5.4)].*

7.2 Lithium

Renal sodium and lithium clearance may be increased during administration of Dextrose and Sodium Chloride Injection resulting in decreased serum lithium concentrations. Monitor serum lithium concentrations during concomitant use.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Appropriate administration of Dextrose and Sodium Chloride Injection during pregnancy is not expected to cause adverse developmental outcomes, including congenital malformations.

Dextrose has been used for decades during labor and delivery. Although there are a few case reports that describe adverse effects of dextrose use in other stages of pregnancy, exposure during pregnancy in general is not expected to cause major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injection.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

8.2 Lactation

Risk Summary

Dextrose has been used for decades and is not expected to cause harm to a breastfed infant. There are no data on the effects of Dextrose Injection on levels of glucose in human milk, on the breastfed infant, or on milk production.

Sodium is present in human breast milk. There are no data on the effects of Dextrose and Sodium Chloride Injection on a breastfed infant or the effects on milk production.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Dextrose and Sodium Chloride Injection and any potential adverse effects on the

breastfed infant from Dextrose and Sodium Chloride Injection or from the underlying maternal condition.

8.4 Pediatric Use

Dextrose and Sodium Chloride Injection is indicated in pediatric patients as a source of water, electrolytes, and calories.

The safety profile of Dextrose and Sodium Chloride Injection in pediatric patients is similar to adults.

Neonates, especially preterm neonates 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.

Dextrose and Sodium Chloride Injection can cause imbalances in fluid and electrolytes in pediatric patients and requires close monitoring of volume status and plasma electrolyte concentrations, particularly in pediatric patients who may have impaired ability to regulate fluids and electrolytes. Pediatric patients are at increased risk for developing hyponatremic encephalopathy *[see Warnings and Precautions (5.4, 5.5, 5.6, 5.7)]*.

In very low birth weight infants, excessive or rapid administration of Dextrose and Sodium Chloride Injection may result in increased serum osmolality and risk of intracerebral hemorrhage.

8.5 Geriatric Use

Dextrose and Sodium Chloride Injection has not been studied in sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients. Geriatric patients are at increased risk of developing hyponatremia and hyponatremic encephalopathy *[see Warnings and Precautions (5.4)]*. In general, the infusion rate for geriatric patients should start slow and be titrated up cautiously, reflecting their greater risk for electrolyte abnormalities and fluid overload.

Dextrose and Sodium Chloride Injection is known to be substantially excreted by the kidney, and the risk of adverse reactions to Dextrose and Sodium Chloride Injection may be greater in patients with impaired renal function *[see Warnings and Precaution (5.6)]*.

Because geriatric patients are more likely to have impaired renal function, care should be taken in selection of infusion rate and patients should be closely monitored during Dextrose and Sodium Chloride Injection treatment.

8.6 Renal Impairment

Administration of Dextrose and Sodium Chloride Injection in patients with renal impairment may result in hyperosmolar hyperglycemic state, hyponatremia, and/or fluid overload. Monitor patients with renal impairment for development of these adverse reactions *[see Warnings and Precautions (5.3, 5.4, 5.5, 5.6, 5.7)]*.

10 OVERDOSAGE

Excessive administration of Dextrose and Sodium Chloride Injection can cause hyperglycemia, hyperosmolality, and adverse effects on fluid and electrolyte balance *[see Warnings and Precautions (5.3, 5.7)]*.

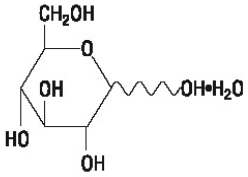
Severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal. In the event of overdosage (overhydration or solute overload) during Dextrose and Sodium Chloride Injection treatment, discontinue the infusion. Institute corrective measures such as administration of

exogenous insulin, and treat adverse effects on the CNS, respiratory, and cardiovascular systems *[see Warnings and Precautions (5.3, 5.7)]*.

11 DESCRIPTION

Dextrose and Sodium Chloride Injection is a clear, sterile, nonpyrogenic solution and contains no bacteriostatic or antimicrobial agents. These products are intended for intravenous administration.

The structural formula and molecular weight of the active ingredients are:

Ingredients	**Structural Formula**	**Molecular Weight**
Sodium Chloride USP	NaCl	58.44
Hydrous Dextrose USP		198.17

Composition, osmolarity, pH, ionic concentration, and caloric content are shown in Table 1.

Table 1

	Size (mL)	Composition (g/100 mL)		*Osmolarity (mOsmol/L) (calc.)	pH	Ionic Concentration (mEq/L)		Caloric Content (kcal/L)
		Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)			Sodium	Chloride	
3.3% Dextrose and 0.30% Sodium Chloride Injection USP	500 1000	3.3 g	0.3 g	270	4.5 (3.5-6.5)	51	51	110
5% Dextrose and 0.90% Sodium Chloride Injection USP	500 1000	5 g	0.9 g	560	4.4 (3.5-6.5)	154	154	170
5% Dextrose and 0.45% Sodium Chloride Injection USP	250 500 1000	5 g	0.45 g	405	4.4 (3.5-6.5)	77	77	170
5% Dextrose and 0.33% Sodium Chloride Injection USP	500 1000	5 g	0.33 g	365	4.4 (3.5-6.5)	56	56	170
5% Dextrose and 0.20% Sodium Chloride Injection USP	250 500 1000	5 g	0.2 g	320	4.4 (3.5-6.5)	34	34	170
10% Dextrose and 0.45% Sodium Chloride Injection USP	1000	10 g	0.45 g	660	4.3 (3.5-6.5)	77	77	340
10% Dextrose and 0.20% Sodium Chloride Injection USP	250	10 g	0.2 g	575	4.3 (3.5-6.5)	34	34	340

* Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.

Dextrose is derived from corn.

Not made with natural rubber latex, PVC or DEHP.

The plastic container is made from a multilayered film developed for parenteral drugs. It contains no plasticizers and exhibits virtually no leachables. The solution contact layer is a rubberized copolymer of ethylene and propylene. The container is nontoxic and biologically inert.

The container-solution unit is a closed system and is not dependent upon entry of external air during administration. The container is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

The closure system has two ports; the one for the administration set has a tamper evident plastic protector and the other is a medication addition site *[see Dosage and Administration (2.2)]*.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Dextrose is a source of carbohydrate calories and is used to supplement nutrition by providing glucose parenterally. Sodium Chloride restores and maintains extracellular fluid volume and osmolality, while supporting membrane potential, nerve and muscle function, and acid-base balance.

12.2 Pharmacodynamics

The exposure-response relationship and time course of pharmacodynamic response for the safety and effectiveness of dextrose and sodium chloride have not been fully characterized.

Dextrose and Sodium Chloride Injection is capable of inducing diuresis depending on the clinical condition of the patient.

12.3 Pharmacokinetics

Dextrose is oxidized to carbon dioxide and water.

Sodium chloride is not metabolized. Sodium and chloride ions are distributed primarily in the extracellular fluid and are excreted by the kidneys.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, genetic toxicology, and animal fertility studies have not been performed with dextrose or sodium chloride.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Dextrose and Sodium Chloride Injections, USP are clear, sterile, and nonpyrogenic solutions supplied in EXCEL® flexible containers as shown in the table below.

REF / Canada DIN	Size (mL)	NDC	Product Name	Package Configuration
L6080-00 / DIN 01927981	1000	0264-7608-00	3.3% Dextrose and 0.3% Sodium Chloride Injection USP	Case of 12
L6081-00 / DIN 01927981	500	0264-7608-10		Case of 24
L6100 / DIN 01924435	1000	0264-7610-00	5% Dextrose and 0.9% Sodium Chloride Injection USP	Case of 12
L6101 / DIN 01924435	500	0264-7610-10		Case of 24
L6120 / DIN 01927531	1000	0264-7612-00	5% Dextrose and 0.45% Sodium Chloride Injection USP	Case of 12
L6121 / DIN 01927531	500	0264-7612-10		Case of 24
L6122 / DIN 01927531	250	0264-7612-20		Case of 24

L6140	1000	0264-7614-00	5% Dextrose and 0.33% Sodium Chloride Injection USP	Case of 12
L6141	500	0264-7614-10		Case of 24
L6160 / DIN 01927558	1000	0264-7616-00	5% Dextrose and 0.2% Sodium Chloride Injection USP	Case of 12
L6161 / DIN 01927558	500	0264-7616-10		Case of 24
L6162 / DIN 01927558	250	0264-7616-20		Case of 24
L6220	1000	0264-7622-00	10% Dextrose and 0.45% Sodium Chloride Injection USP	Case of 12
L6232	250	0264-7623-20	10% Dextrose and 0.2% Sodium Chloride Injection USP	Case of 24

Storage and Handling:

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature.]

Minimize Exposure of Dextrose and Sodium Chloride Injection to heat. Avoid excessive heat. Protect from freezing.

EXCEL is a registered trademark of B. Braun Medical Inc.

Rx only

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