HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DEXTROSE INJECTION (5%) safely and effectively. See full prescribing information for DEXTROSE INJECTION (5%).

DEXTROSE Injection, for intravenous use
Initial U.S. Approval: 1940

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

Dosage and Administration (2.1, 2.2, 2.3)	05/2026
Contraindications (4)	05/2026
Warnings and Precautions (5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7)	05/2026

----------INDICATIONS AND USAGE----------

Dextrose Injection (5%) is indicated as a source of water and calories in adult and pediatric patients, and may also be used as a diluent for reconstitution of a powder or liquid drug product. (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:

- 5% (5 g/100 mL) (50 mg/mL) of dextrose hydrous in single-dose partial-fill flexible containers: 25 mL volume in 100mL, 50 mL volume in 100 mL, 100 mL volume in 150 mL. (3)

----------CONTRAINDICATIONS----------

- Clinically significant hyperglycemia. (4)
- Known hypersensitivity to dextrose. (4)

----------WARNINGS AND PRECAUTIONS----------

- Neonatal Hypoglycemia: Closely monitor blood glucose concentrations to ensure adequate glycemic control. (5.1)
- Hyperglycemia and Hyperosmolar Hyperglycemic State: Use with caution in patients with known subclinical or overt diabetes mellitus. (5.2)
- Hypersensitivity Reactions: Monitor for signs and symptoms and discontinue infusion immediately if reaction occurs. (5.3)
- Phlebitis and Thrombosis: Remove catheter as soon as possible if thrombophlebitis develops. (2.1, 5.4)
- Hyponatremia: Monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and neurologic status. (5.5)
- Electrolyte Imbalance and Fluid Overload: Monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during administration. (5.6)
- Refeeding Syndrome: Monitor laboratory parameters. (5.7)

----------ADVERSE REACTIONS----------

The most common adverse reactions are hyperglycemia, hypersensitivity reactions, hyponatremia, infection, both systemic and at the injection site, vein thrombosis or phlebitis, and electrolyte imbalance. (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 and Electrolyte Balance: Monitor blood glucose concentrations, fluid balance, serum electrolyte concentrations, and acid-base balance. Avoid use of Dextrose Injection in patients receiving drugs associated with hyponatremia. (7.1)

----------USE IN SPECIFIC POPULATIONS----------

Pediatric Use: Increased risk of hypoglycemia/hyperglycemia and imbalances in fluid/electrolytes; monitor serum glucose concentrations, volume status, and electrolytes. (8.4)

Revised: 5/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Dextrose Injection (5%) is indicated as a source of water and calories in adult and pediatric patients, and may also be used as a diluent for reconstitution of a powder or liquid drug product.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

Dextrose Injection (5%) 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 (5.4)]*.
- Avoid administering Dextrose Injection (5%) 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.
- It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.
- Discard the unused portion.
- Avoid use with chemotherapy agents. Consult the specific chemotherapy agent prescribing information to determine the appropriate diluent.

2.2 Important Preparation Information

Visually inspect the Dextrose Injection (5%) for particulate matter and discoloration. Do not administer 5% Dextrose Injection if the solution is cloudy, there are precipitates, or the container is damaged.

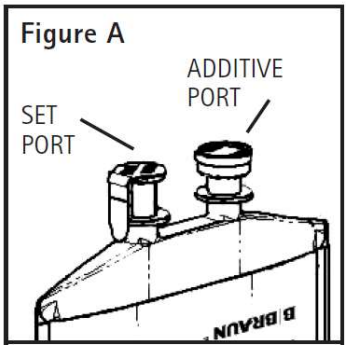
To reduce the risk of air embolism, adhere to the following preparation instructions for 5% Dextrose Injection:

- 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.
- If using a pumping device to administer Dextrose Injection (5%), turn off the pump before the container is empty.

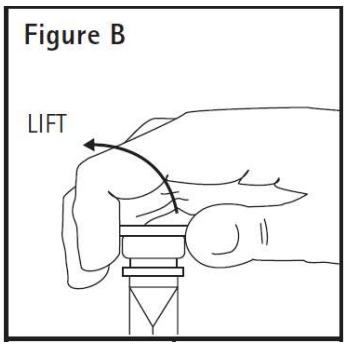
If additives are determined to be compatible with Dextrose Injection (5%) then using aseptic technique, mix thoroughly; do not store solutions containing additives. After mixing, do not use if there is discoloration or formation of precipitates.

To Add Medication

1. **Identify Two Ports (See Figure A).**



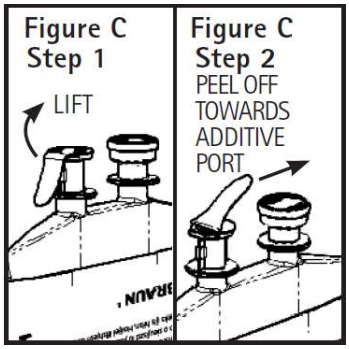
2. **To Add Medication**



Remove additive port closure: hold container below additive port and grasp cap between thumb and forefinger then flip cap upward **(See Figure B). Swab exposed additive port.** Using a syringe with 18 gauge or smaller needle, insert cannula through resealable additive port and add desired drug. Mix thoroughly.

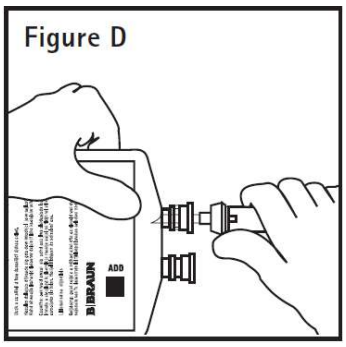
Note: Partial fill bags have been designed to accept an overfill of up to 50 mL.

3. **To Attach Administration Set**



To aseptically remove the set port closure: hold container below the set port and grasp the foil tab between the thumb and forefinger then pull the tab in two steps as shown in **Figure C Steps 1 and 2**.

4.



Push spike through the diaphragm of the port **(See Figure D)**. Hang container using hole on the lower flap. Prime set in accordance with the instructions provided with the set in use *[see Important Preparation Instructions (2.2)]*.

When the container is to be used as a diluent and delivery system for intermittent intravenous administration of compatible drug additives, consult prescribing information for drug additives to be administered in this manner.

2.3 Dosage Considerations

The choice of dextrose concentration, rate, and volume depends on the age, weight, clinical and metabolic conditions of the patient and concomitant therapy.

Dextrose Injection (5%) administration rate should be based on the patient's tolerance of dextrose, especially for preterm neonates with low birth weight.

Increase the infusion rate gradually as needed; frequently monitor blood glucose concentrations to avoid hyperglycemia *[see Warnings and Precautions (5.2), Use in Specific Populations (8.4)]*.

3 DOSAGE FORMS AND STRENGTHS

Injection:

- 5% (5 g/100 mL) (50 mg/mL) of dextrose hydrous in a clear, sterile, and nonpyrogenic solution in single-dose partial-fill flexible containers: 25 mL volume in 100 mL, 50 mL volume in 100 mL, 100 mL volume in 150 mL.

4 CONTRAINDICATIONS

Dextrose Injection (5%) is contraindicated in patients with:

- Clinically significant hyperglycemia *[see Warnings and Precautions (5.2)]*.
- Known hypersensitivity to dextrose *[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 Injection (5%) to ensure adequate glycemic control in order to avoid potential long-term adverse effects.

5.2 Hyperglycemia and Hyperosmolar Hyperglycemic State

The use of Dextrose Injection (5%) 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 (5.6), Use in Specific Populations (8.4)]*. Patients with underlying CNS disease and renal impairment who receive dextrose infusions may be at greater risk of developing hyperosmolar hyperglycemic state.

Monitor blood glucose levels and treat hyperglycemia to maintain levels within normal limits while administering Dextrose Injection (5%). Insulin may be administered or adjusted to maintain optimal blood glucose levels during Dextrose Injection (5%) administration.

5.3 Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, have been reported with Dextrose Injection (5%) administration *[see Adverse Reactions (6)]*. Stop administration of Dextrose Injection (5%) immediately if signs or symptoms of a hypersensitivity reaction develop. Initiate appropriate treatment as clinically indicated.

5.4 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.

5.5 Hyponatremia

Dextrose Injection (5%) may cause hyponatremia. Hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy, and vomiting. 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)]*.

Avoid Dextrose Injection (5%) 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 (5.6)]*.

5.6 Electrolyte Imbalance and Fluid Overload

Electrolyte deficits, particularly serum potassium and phosphate, may occur during prolonged use of Dextrose Injection (5%).

Depending on the administered volume and the infusion rate, Dextrose Injection (5%) can cause fluid overload, including pulmonary edema.

Avoid Dextrose Injection (5%) in patients at risk for fluid and/or solute overload. If use cannot be avoided in these patients, 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.

5.7 Refeeding Syndrome

Refeeding severely undernourished patients may result in refeeding syndrome, characterized by the intracellular shift of potassium, phosphorus, and magnesium 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

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Neonatal Hypoglycemia *[see Warnings and Precautions (5.1)]*
- Hyperglycemia and Hyperosmolar Hyperglycemic State *[see Warnings and Precautions (5.2)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.3)]*
- Phlebitis and Thrombosis *[see Warnings and Precautions (5.4)]*
- Hyponatremia *[see Warnings and Precautions (5.5)]*
- Electrolyte Imbalance and Fluid Overload *[see Warnings and Precautions (5.6)]*
- Refeeding syndrome *[see Warnings and Precautions (5.7)]*

The following adverse reactions associated with the use of Dextrose Injection (5%) 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, pruritis, pyrexia, rash

Cardiovascular disorders: cyanosis, volume overload

7 DRUG INTERACTIONS

7.1 Effects on Glycemic Control and Electrolyte Balance

Dextrose Injection (5%) can affect glycemic control, vasopressin, and fluid and/or electrolyte balance *[see Warnings and Precautions (5.1, 5.2, 5.5, 5.6)]*. Monitor patients' blood glucose concentrations, fluid balance, serum electrolyte concentrations, and acid-base balance.

Concomitant administration of Dextrose Injection (5%) 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 Injection (5%) in patients receiving drugs associated with hyponatremia. If use cannot be avoided, closely monitor serum sodium concentrations during concomitant use *[see Warnings and Precautions (5.5)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Dextrose Injection (5%) 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.

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 Injection (5%) 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 (5%) on levels of glucose in human milk, on the breastfed infant, or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Dextrose Injection (5%) and any potential adverse effects on the breastfed infant from Dextrose Injection (5%) or from the underlying maternal condition.

8.4 Pediatric Use

Dextrose Injection (5%) is indicated in pediatric patients as a source of water and calories, and may also be used as a diluent for reconstitution of a powder or liquid drug product.

Neonates, especially preterm neonates with low birth weight, are at increased risk of developing hypo-or hyperglycemia. Therefore, they need close monitoring during treatment with intravenous glucose infusions to ensure adequate glycemic control in order to avoid potential long-term adverse effects.

Dextrose Injection (5%) 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 (5.5, 5.6)]*.

In very low birth weight neonates, excessive or rapid administration of Dextrose Injection (5%) may result in increased serum osmolality and risk of intracerebral hemorrhage.

8.5 Geriatric Use

Dextrose Injection (5%) has not been studied in sufficient number 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 (5.5)].* Other reported clinical experience has not identified differences in responses between the geriatric and younger adult patients. 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 is known to be substantially excreted by the kidney, and the risk of adverse reactions to Dextrose Injection (5%) may be greater in patients with impaired renal function. 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 Injection (5%) treatment.

10 OVERDOSAGE

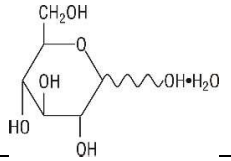
A medication error resulting in a high infusion rate of Dextrose Injection (5%) can cause hyperglycemia, hyperosmolality, and adverse effects on fluid and electrolyte *balance [see Warnings and Precautions (5.2, 5.6)]*.

Severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal. In the event of overdosage (overhydration or solute overload) during Dextrose Injection (5%) 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 (5.2, 5.6)]*.

11 DESCRIPTION

Dextrose Injection USP (5%) is a sterile, nonpyrogenic, and isotonic solution and contains no bacteriostatic or antimicrobial agents. This product is intended for intravenous administration.

The formula of the active ingredient is:

Ingredient	Molecular Formula	Molecular Weight
Hydrous Dextrose USP		198.17

Each mL of Dextrose Injection USP (5%) contains:
Hydrous Dextrose USP 50 mg; Water for Injection USP qs

pH: 4.5 (3.5-6.5)

Calculated Osmolarity: 250 mOsmol/liter

Calories per 100 mL: 17

Dextrose is derived from corn.

Not made with natural rubber latex, PVC, or DEHP.

The plastic container is a copolymer of ethylene and propylene formulated and developed for parenteral drugs. The copolymer contains no plasticizers and exhibits virtually no leachability. The safety of the plastic container has been confirmed by biological evaluation procedures. The material

passes Class VI testing as specified in the U.S. Pharmacopeia for Biological Tests — Plastic Containers. These tests have shown that 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 has two ports, one is for the intravenous administration set and the other is a medication addition site. Each is covered by a tamperproof barrier *[see Dosage and Administration (2.2)].*

No vapor barrier is necessary.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Dextrose provides a source of carbohydrate calories and is used to supplement nutrition by providing glucose parenterally.

12.2 Pharmacodynamics

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

12.3 Pharmacokinetics

Dextrose is oxidized to carbon dioxide and water.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with dextrose to evaluate the drug's carcinogenic potential, mutagenic potential, or effects on fertility have not been performed.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

5% Dextrose Injection, USP is a clear, sterile, and nonpyrogenic solution supplied in partial fill polyolefin containers as shown in table below.

NDC No.	REF	Each (5% Dextrose Injection)	Package Configuration
0264-1510-36	S5104-5410	25 mL in a 100 mL partial fill container	Case of 116
0264-1510-31	S5104-5384	50 mL in a 100 mL partial fill container	Case of 84
0264-1510-32	S5104-5264	100 mL in a 150 mL partial fill container	Case of 64

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 Injection, USP (5%) to heat. Avoid excessive heat. Protect from freezing.

Rx only

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Y36-003-109 LD-213-7