HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DEXTROSE INJECTION (5% and 10%) safely and effectively. See full prescribing information for DEXTROSE INJECTION (5% and 10%).

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

----------RECENT MAJOR CHANGES----------
Warnings and Precautions (5.1) 06/2026

----------INDICATIONS AND USAGE----------
Dextrose Injection (5% and 10%) is indicated as a source of water and calories in adults 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 information on preparation, administration, 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, 50 mL, 100 mL, 250 mL, 500 mL, and 1000 mL. (3)
- 10% (10 g/100 mL)(100 mg/mL) of dextrose hydrous in partial-fill flexible containers: 250 mL, 500 mL, and 1000 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 or 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 reactions occur. (5.3)
- Phlebitis and Thrombosis: Remove catheter as soon as possible if thrombophlebitis develops. (2.2, 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 Baxter Healthcare at 1-866-888-2472 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: 06/2026

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% and 10%) is indicated as 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% and 10%) 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% and 10%) 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.
- Use promptly; do not store solutions containing additives.
- Discard the unused portion.
- To determine if chemotherapy agents are compatible with dextrose solutions, consult the specific chemotherapy agent prescribing information to determine if dextrose is the appropriate diluent.

2.2 Important Preparation Information

Visually inspect the Dextrose Injection (5% and 10%) for particulate matter and discoloration. Do not administer Dextrose Injection (5% and 10%) 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 Injection (5% and 10%):

• 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).

• 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 Injection (5% and 10%), turn off the pump before the container is empty.

To Open

- Do not remove from overpouch until ready to use.
- Tear overwrap down side at slit and remove solution container. Small amounts of moisture may be found on the solution container from water permeating from inside the container. The amount of permeated water is insufficient to affect the solution significantly. If larger amounts of water are found, the container should be checked for tears or leaks.
- 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 the 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 set.

To Add Medication

- Additives may be incompatible. Complete information is not available. Do not use additives known or determined to be incompatible.
- Consult with pharmacist, if available. If, in the informed judgment of the healthcare provider, it is deemed advisable to introduce additives, use aseptic technique.
- When introducing additives, consult the instructions for use of the medication to be added and other relevant literature.
- Before adding a substance or medication, verify that it is soluble and/or stable in Dextrose Injection and that the pH range of Dextrose Injection is appropriate.

To Add Medication Before Solution Administration

1. Prepare medication site.
2. Using syringe with 19 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 19 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 administration.

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% and 10%) patients' tolerance of dextrose, especially for premature infants 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 a clear, sterile, non-pyrogenic solution in single-dose partial-fill flexible containers: 25 mL, 50 mL, 100 mL, 250 mL, 500 mL, and 1000 mL
- 10% (10 g/100 mL) (100 mg/mL) of dextrose hydrous in sing-dose partial-fill flexible containers: 250 mL, 500 mL, and 1000 mL

4 CONTRAINDICATIONS

Dextrose Injection (5% and 10%) 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% and 10%) 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% and 10%) 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% and 10%). Insulin may be administered or adjusted to maintain optimal blood glucose levels during Dextrose Injection (5% and 10%) administration.

5.3 Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, have been reported with Dextrose Injection (5% and 10%) administration *[see Adverse Reactions (6)]*. Stop administration 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% and 10%) 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% and 10%) in patients with or at risk for hyponatremia. If use cannot be avoided, 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% and 10%).

Depending on the administered volume and infusion rate, Dextrose Injection (5% and 10%) can cause fluid overload, including pulmonary edema.

Avoid Dextrose Injection (5% and 10%) in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor fluid balance, electrolyte concentrations, 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 were identified in clinical trials or postmarketing reports. Because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency, reliably, or to 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% and 10%) can affect glycemic control, vasopressin, and fluid and/or electrolyte balance *[see Warnings and Precautions (5.1, 5.2, 5.4, 5.5)]*. Monitor patient's blood glucose concentrations, fluid balance, serum electrolyte concentrations and acid-base balance.

Concomitant administration of Dextrose Injection (5% and 10%) 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% and 10%) 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% and 10%) 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% and 10%) 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% and 10%) 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 10%) and any potential adverse effects on the breastfed infant from Dextrose Injection (5% and 10%) or from the underlying maternal condition.

8.4 Pediatric Use

Dextrose Injection (5% and 10%) 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 premature infants 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% and 10%) 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 infants, excessive or rapid administration of Dextrose Injection (5% and 10%) may result in increased serum osmolality and risk of intracerebral hemorrhage.

8.5 Geriatric Use

Dextrose Injection (5% and 10%) has not been studied insufficient 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 as well as for developing 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 low and be titrated up cautiously, reflecting their greater risk for electrolyte abnormalities and fluid overload.

Dextrose Injection (5% and 10%) is known to be substantially excreted by the kidney, and the risk of adverse reactions to Dextrose Injection (5% and 10%) 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% and 10%) treatment.

10 OVERDOSAGE

A medication error resulting in a high infusion rate of Dextrose Injection (5% and 10%) 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% and 10%) 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, 5% and 10% USP are sterile, non-pyrogenic solutions of Dextrose, USP in Water for Injection in a polyvinylchloride flexible plastic container for intravenous administration as a source of water and calories.

Partial-fill containers, designed to facilitate admixture when necessary, are available in 25 mL, 50 mL, 100 mL, , 250 mL, 500 mL, and 1000 mL sizes. See Table 1 for the content and characteristics of this solution.

The solution contains no bacteriostatic, antimicrobial agent or added buffer and is intended only for use as a single-dose injection. The pH range is 4.0 (3.2 to 6.5).

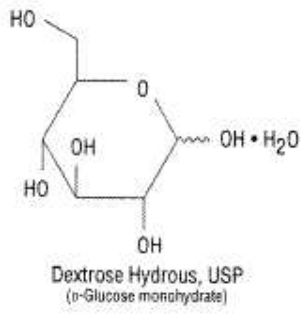
Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly.

Table 1. Contents and Characteristics of Dextrose Injection 5% and 10%, USP

Strength	Fill Volume	Amount of Dextrose Hydrous per Container	kcal* per Container	Osmolarity (mOsmol per liter)
Dextrose Injection 5%, USP (0.05 grams/mL)	25 mL Quad pack	1.25 grams	4.25	252
	50 mL Single pack Quad pack Multi pack	2.5 grams	8.5	252
	100 mL Single pack Quad pack Multi pack	5 grams	17	252
	250 mL	12.5 grams	42.5	252
	500 mL	25 grams	85	252
	1000 mL	50 grams	170	252
Dextrose Injection 10%, USP (0.1 grams/mL)	250 mL	25 grams	85	505
	500 mL	50 grams	170	505
	1000 mL	100 grams	340	505

*Caloric value calculated on the basis of 3.4 kcal/g of dextrose, hydrous

Dextrose, USP is chemically designated D-glucose, monohydrate ($C_6H_{12}O_6 \cdot H_2O$), a hexose sugar freely soluble in water. The molecular weight of dextrose (D-glucose) monohydrate is 198.17. It has the following structural formula:



Water for Injection, USP is chemically designated H_2O.

Dextrose is derived from corn.

The VIAFLEX Plus plastic container is fabricated from polyvinyl chloride (PL 146 Plastic). VIAFLEX Plus on the container indicates the presence of a drug additive in a

drug vehicle. The VIAFLEX Plus plastic container system utilizes the same container as the VIAFLEX plastic container system. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution. Solutions in contact with the plastic container can leach out certain of its chemical components in small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. The safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

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

Dextrose Injection (5% and 10%), USP is clear, colorless, sterile solutions of dextrose supplied in a single-dose, partial-fill flexible containers.

Product Description	Size	Code	NDC
Dextrose Injection 5%, USP (5 g/100 mL) (50 mg/mL)	25 mL Quad pack	2B0080	0338-0017-10

	50 mL Single pack Quad pack Multi pack	 2B0086 2B0081 2B0088	 0338-0017-41 0338-0017-11 0338-0017-31
	100 mL Single pack Quad pack Multi pack	 2B0087 2B0082 2B0089	 0338-0017-48 0338-0017-18 0338-0017-38
	250 mL 500 mL 1000 mL	2B0062 2B0063 2B0064	0338-0017-02 0338-0017-03 0338-0017-04
Dextrose Injection 10%, USP (10 g/100 mL) (100 mg/mL)	250 mL 500 mL 1000 mL	2B0162 2B0163 2B0164	0338-0023-02 0338-0023-03 0338-0023-04

Do not remove container from the overwrap until intended for use.

Use the product immediately after mixing and the introduction of additives.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F); brief exposure up to 40°C/104°F does not adversely affect the product.

Manufactured by, Packed by, Distributed by:

Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Printed in USA