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

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

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

Contraindications (4)	08/2019
Warnings and Precautions (5.1, 5.2, 5.3, 5.4, 5.5, 5.6)	08/2019

----------INDICATIONS AND USAGE----------
Dextrose Injection is indicated as a source of water and calories. (1)

----------DOSAGE AND ADMINISTRATION----------
- Only for intravenous infusion. (2.1)
- See full prescribing information for information on preparation, administration, dosing considerations and instructions for use. (2.1, 2.2, 2.3)

----------DOSAGE FORMS AND STRENGTHS----------
Injection:
- 5% (0.05 grams/mL): 5 grams of dextrose hydrous per 100 mL in single-dose partial-fill flexible containers: 25 mL, 50 mL, 100 mL, 150 mL, 250 mL, 500 mL, and 1000 mL. (3)
- 10% (0.1 grams/mL): 10 grams of dextrose hydrous per 100 mL 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----------
- Hyperglycemia or Hyperosmolar Hyperglycemic State: Monitor blood glucose and administer insulin as needed. (5.1)
- Hypersensitivity Reactions: Monitor for signs and symptoms and discontinue infusion if reactions occur. (5.2)
- Vein Damage and Thrombosis: Consider central vein when administering more than 5% dextrose or with an osmolarity of at least 900 mOsm/L or when there is peripheral vein irritation, phlebitis, and/or associated pain. (2.2, 5.3)
- Hyponatremia: Avoid in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations. (5.4)
- Electrolyte Imbalance and Fluid Overload: Avoid in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor daily fluid balance, electrolyte concentrations, and acid-base balance, as needed and especially during prolonged use. (5.5)
- Refeeding Syndrome: Monitor severely undernourished patients and slowly increase nutrient intake. (5.6)

----------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 ----------
Other Products that Affect Glycemic Control, Vasopressin or Fluid and/or Electrolyte Balance: Monitor blood glucose concentrations, fluid balance, serum electrolyte concentrations and acid-base balance. (7.1)

----------USE IN SPECIFIC POPULATIONS----------
Pediatric Use: Increased risk of hypoglycemia/hyperglycemia; monitor serum glucose concentrations. (8.4)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 08/2019

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Dextrose Injection is indicated as source of water and calories.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

- Dextrose Injection is intended for intravenous use.
- Peripheral administration of 5% dextrose is generally acceptable, however, consider central vein when administering more than 5% dextrose or with an osmolarity of at least 900 mOsm/L or when there is peripheral vein irritation, phlebitis, and/or associated pain *[see Warnings and Precautions (5.3)]*.
- Do not administer Dextrose Injection simultaneously with blood products through the same administration set because of the possibility of pseudoagglutination or hemolysis.
- To prevent air embolism, use a non-vented infusion set or close the vent on a vented set, avoid multiple connections, do not connect flexible containers in series, fully evacuate residual gas in the container prior to administration, do not pressurize the flexible container to increase flow rates, and if administration is controlled by a pumping device, turn off pump before the container runs dry.
- Prior to infusion, visually inspect the diluted dextrose solution for particulate matter. The solution should be clear and there should be no precipitates. Do not administer unless solution is clear and container is undamaged.
- Use of a final filter is recommended during administration of parenteral solutions, where possible.

2.2 Recommended Dosage

The choice of dextrose concentration, 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 premature infants 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)]*.

2.3 Instructions for Use

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.

Storage

- Use promptly; do not store solutions containing additives.

- Single-dose container.
- Discard any unused portion.

3 DOSAGE FORMS AND STRENGTHS

Dextrose Injection, USP is a clear, sterile, non-pyrogenic solution of dextrose in single-dose containers:

- 5% (0.05 grams/mL): 5 grams of dextrose hydrous per 100 mL in partial-fill flexible containers: 25 mL, 50 mL, 100 mL, 150 mL, 250 mL, 500 mL, and 1000 mL
- 10% (0.1 grams/mL): 10 grams of dextrose hydrous per 100 mL in partial-fill flexible containers: 250 mL, 500 mL, and 1000 mL

4 CONTRAINDICATIONS

The use of Dextrose Injection is contraindicated in patients with:

- Clinically significant hyperglycemia *[see Warnings and Precautions (5.1)]*.
- Known hypersensitivity to dextrose *[see Warnings and Precautions (5.2)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Hyperglycemia and Hyperosmolar Hyperglycemic State

The use of dextrose infusions 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 (5.5)]*. 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. Insulin may be administered or adjusted to maintain optimal blood glucose levels during Dextrose Injection administration.

5.2 Hypersensitivity Reactions

Hypersensitivity and infusion reactions, including anaphylaxis, have been reported with Dextrose Injection *[see Adverse Reactions (6)]*. Stop infusion immediately and treat patient accordingly if signs or symptoms of a hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

5.3 Vein Damage and Thrombosis

Peripheral administration of 5% Dextrose Injection is generally acceptable, however, consider central vein when administering more than 5% dextrose or with an osmolarity of ≥ at least 900 mOsm/L or when there is peripheral vein irritation, phlebitis, and/or associated pain *[see Dosage and Administration (2. 1)]*. The infusion of hypertonic solutions into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis. The primary complication of peripheral access is venous thrombophlebitis, which manifests as pain, erythema, tenderness or a palpable cord. Remove the catheter as soon as possible, if thrombophlebitis develops.

5.4 Hyponatremia

10% Dextrose Injection is a hypertonic solution *[see Description, Table 1 (11)]*. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization. Monitoring of serum sodium is particularly important for hypotonic fluids.

Depending on the tonicity of the solution, the volume and rate of infusion, and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances, most importantly hypo- or hyperosmotic hyponatremia. Monitor serum sodium to minimize the risk of hyponatremia.

The risk for hyponatremia is increased in pediatric patients, elderly patients, postoperative patients, those with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (such as diuretics, certain antiepileptic and psychotropic medications). Close clinical monitoring may be warranted.

Acute hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury. Patients at increased risk for developing complications of hyponatremia, such as hyponatremic encephalopathy include pediatric patients; women, in particular, premenopausal women; patients with hypoxemia; and in patients with underlying central nervous system disease *[see Use in Specific Populations (8.4, 8.5)]*.

Avoid Dextrose Injection in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations.

Rapid correction of hyponatremia is potentially dangerous with risk of serious neurologic complications. Brain adaptations reducing risk of cerebral edema make the brain vulnerable to injury when chronic hyponatremia is too rapidly corrected, which is known as osmotic demyelination syndrome (ODS). To avoid complications, monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and signs of neurologic complications.

High volume infusion must be used with close monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatremia.

5.5 Electrolyte Imbalance and Fluid Overload

Electrolyte deficits, particularly in serum potassium and phosphate, may occur during prolonged use of concentrated dextrose solutions.

Depending on the volume and rate of infusion, the patient's underlying clinical condition and capability to metabolize dextrose, intravenous administration of Dextrose Injection can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, (including hypoosmotic hyponatremia), overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations in the administered solution. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations in the solution.

Avoid Dextrose Injection in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor fluid balance, blood electrolyte levels, concentration of glucose, acid-base balance, correct fluid and electrolyte imbalances during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation and acid-base balance as needed and 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. Patients at increased risk for developing hyponatremic encephalopathy include pediatric patients; elderly patients, women, in particular premenopausal women; patients with hypoxemia; and patients with underlying CNS disease *[see Use in Specific Populations (8.4, 8.5)]*.

5.6 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 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.

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

- Hyperglycemia and hyperosmolar hyperglycemic state *[see Warnings and Precautions (5.1)]*
- *Hypersensitivity Reactions*: anaphylaxis, pruritis, bronchospasm, cyanosis, angioedema, hypotension, pyrexia, chills, and rash *[see Warnings and Precautions (5.2)]*
- *Infusion Site Reactions*: infusion site phlebitis, infusion site erythema, vein damage and thrombosis, and infusion site thrombophlebitis (10% dextrose only) *[see Warnings and Precautions (5.3)]*
- Hyponatremia and hyponatremic encephalopathy *[see Warnings and Precautions (5.4)]*
- Electrolyte imbalance, fluid overload and hypervolemia *[see Warnings and Precautions (5.5)]*
- Refeeding syndrome *[see Warnings and Precautions (5.6)]*
- Pulmonary vascular precipitates (10% dextrose only)

7 DRUG INTERACTIONS

7.1 Other Products that Affect Glycemic Control, Vasopressin or Fluid and/or Electrolyte Balance

Dextrose Injection can affect glycemic control, vasopressin and fluid and/or electrolyte balance *[see Warnings and Precautions (5.1, 5.4, 5.5)]*. Monitor blood glucose concentrations, fluid balance, serum electrolyte concentrations and acid-base balance when using Dextrose Injection in patients treated with other substances that affect glycemic control, vasopressin or fluid and/or electrolyte balance.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Appropriate administration of Dextrose Injection during pregnancy is not expected to cause adverse developmental outcomes, including congenital malformations. Animal reproduction studies have not been conducted with injectable dextrose solutions.

The estimated 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

There are no data on the presence of dextrose in human milk, the effects on a breastfed infant, or the effects on milk production. The lack of clinical data during lactation precludes a clear determination of the risk of Dextrose Injection to an infant during lactation; therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Dextrose Injection and any potential adverse effects on the breastfed infant from Dextrose Injection or from the underlying maternal condition.

8.4 Pediatric Use

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

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

Closely monitor plasma electrolyte concentrations in pediatric patients who may have impaired ability to regulate fluids and electrolytes. In very low birth weight infants, excessive or rapid administration of Dextrose Injection may result in increased serum osmolality and risk of intracerebral hemorrhage.

Children (including neonates and older children) are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy *[see Warnings and Precautions (5.4)]*.

8.5 Geriatric Use

Clinical studies of Dextrose Injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Elderly patients are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy *[see Warnings and Precautions (5.4)]*. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Dextrose is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

10 OVERDOSAGE

An increased infusion rate of Dextrose Injection or administration of dextrose solutions can cause hyperglycemia, hyperosmolality, and adverse effects on water and electrolyte balance *[see Warnings and Precautions (5.1, 5.5)]*.

Severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal. Discontinue infusion, reduce dose and institute appropriate corrective measures such as administration of exogenous insulin.

Discontinue infusion and institute appropriate corrective measures in the event of overhydration or solute overload during therapy, with particular attention to CNS, respiratory and cardiovascular systems.

If over-exposure occurs, call your Poison Control Center at 1-800-222-1222 for current information on the management of poisoning or overdosage.

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, 150 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).

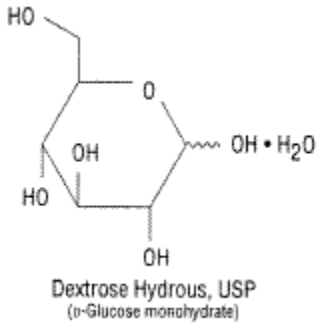
Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly.

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
	150 mL	7.5 grams	25.5	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:



Dextrose Hydrous, USP
(D-Glucose monohydrate)

Water for Injection, USP is chemically designated H_2O.

Dextrose is derived from corn.

The VIAFLEX Plus plastic container is fabricated from a specially formulated 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 significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, 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 is oxidized to carbon dioxide and water, yielding energy.

16 HOW SUPPLIED/STORAGE AND HANDLING

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

Product Description	Size	Code	NDC
Dextrose Injection 5%, USP (0.05 grams/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
	150 mL 250 mL 500 mL 1000 mL	2B0061 2B0062 2B0063 2B0064	0338-0017-01 0338-0017-02 0338-0017-03 0338-0017-04
Dextrose Injection 10%, USP (0.1 grams/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.

Store between 20ºC to 25°C (68º F to 77°F). [See USP controlled room temperature.]

Do not freeze.

17 PATIENT COUNSELING INFORMATION

Inform patients, caregivers, or home healthcare providers of the following risks of Dextrose Injection:

- Hyperglycemia and hyperosmolar hyperglycemic state *[see Warnings and Precautions (5.1)]*
- Hypersensitivity reactions *[see Warnings and Precautions (5.2)]*
- Vein damage and thrombosis *[see Warnings and Precautions (5.3)]*
- Hyponatremia *[see Warnings and Precautions (5.4)]*
- Electrolyte imbalance and fluid overload *[see Warnings and Precautions (5.5)]*
- Refeeding syndrome *[see Warnings and Precautions (5.6)]*

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HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DEXTROSE INJECTION 70% safely and effectively. See full prescribing information for DEXTROSE INJECTION 70%.

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

----------INDICATIONS AND USAGE----------
Dextrose Injection is indicated as a source of calories when mixed with amino acids or other compatible intravenous fluids for patients requiring parenteral nutrition when oral or enteral nutrition is not possible, insufficient or contraindicated. (1)

----------DOSAGE AND ADMINISTRATION----------
- *Pharmacy Bulk Package. Not for direct intravenous infusion.* (2.1)
- For slow intravenous infusion only into a: (2.2)
  - Central vein, if final dextrose concentration is greater than 5% or osmolality is greater than 900 mOsm/L approximately.
  - Peripheral vein, if final dextrose concentration 5% or less and osmolality is less than 900 mOsm/L approximately.
- Individualize dosage based on the patient's clinical condition, body weight, nutritional/fluid requirements, as well as additional energy given orally/enterally. (2.3)
- Discontinue infusion of concentrated dextrose solutions slowly. (2.4)

----------DOSAGE FORMS AND STRENGTHS----------
- Injection: 70% (0.7 grams/mL), 70 grams of dextrose hydrous per 100 mL in a 2000 mL Pharmacy Bulk Package flexible container. (3)

----------CONTRAINDICATIONS----------
Severe dehydration. (4)

----------WARNINGS AND PRECAUTIONS----------
- Pulmonary Embolism due to Pulmonary Vascular Precipitates: If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation. (5.1)
- Hyperglycemia or Hyperosmolar Hyperglycemic State: Monitor blood glucose and administer insulin as needed. (5.2)
- Hypersensitivity Reactions: Monitor for signs and symptoms and discontinue infusion if reactions occur. (5.3)
- Vein Damage and Thrombosis: Administer solutions containing more than 5% dextrose as the final concentration or solutions with an osmolarity of approximately 900 mOsm/L or greater through a central vein. (2.2, 5.4)
- Hyponatremia: Monitor serum sodium to minimize the risk of hypo- or hyperosmotic hyponatremia. (5.5)
- Risk of Infection: Monitor for signs and symptoms and laboratory parameters. (5.6)
- Refeeding Syndrome: Monitory laboratory parameters. (5.7)
- Hepatobiliary Disorders: Monitor liver function parameters and ammonia levels. (5.8)
- Aluminum Toxicity: Dextrose Injection contains aluminum that may be toxic. Adult patients with impaired renal function and preterm infants are at higher risk. Limit aluminum to less than 4 mcg/kg/day (5.9, 8.4)
- Parenteral Nutrition Associated Liver Disease: Increased risk in patients who receive parenteral nutrition for extended periods of time, especially preterm infants; monitor liver function tests, if abnormalities occur consider discontinuation or dosage reduction. (5.10, 8.4)
- Electrolyte Imbalance and Fluid Overload: Monitor daily fluid balance, blood electrolyte levels, correct as needed. (5.11, 8.4)

----------ADVERSE REACTIONS----------
The most common adverse reactions are, hyperglycemia, hypersensitivity reactions, infection both systemic and at the injection site, and vein thrombosis or phlebitis. (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 ----------
Other Products that Affect Glycemic Control, Vasopressin or Fluid and/or Electrolyte Balance: Monitor blood glucose concentrations, fluid balance serum electrolyte concentrations and acid-base balance. (7.1)

----------USE IN SPECIFIC POPULATIONS----------
Pediatric Use: Increased risk of hypoglycemia/hyperglycemia; monitor serum glucose concentrations. (8.4)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 07/2019

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Dextrose Injection is indicated as source of calories and fluid replenishment when mixed with amino acids or other compatible intravenous fluids for patients requiring parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient or contraindicated.

2 DOSAGE AND ADMINISTRATION

2.1 Preparation Instructions Prior to Administration

Dextrose Injection is supplied as a pharmacy bulk package *for admixing only* and is *not for direct intravenous infusion.* Dextrose Injection is intended for use in the preparation of sterile, intravenous admixtures. Prior to administration, Dextrose Injection *must be transferred to a separate PN container, diluted* with other compatible intravenous fluids and *used as an admixture* in PN solutions.

- Do not remove from overpouch until ready to use.
- Tear protective overwrap 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.
- Inspect Dextrose Injection prior to use. Opacity of the container may be observed due to moisture absorption during the sterilization process. 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 as solution path sterility may be impaired.
    - Check for minute leaks by squeezing the inner container firmly. If leaks are found, discard solution as sterility may be impaired.
    - Do not use unless solution is clear and container is intact.
- Because additives may be incompatible, evaluate all additions for compatibility and stability of the resulting preparation. Consult with a pharmacist, if available. If it is deemed advisable to introduce additives, use aseptic technique and mix thoroughly.

- Calcium and phosphate ratios must be considered. Excess addition of calcium and phosphate, especially in the form of mineral salts, may result in the formation of calcium phosphate precipitates *[see Warnings and Precautions (5.1)]*.

Preparation for Admixing

1. The Pharmacy Bulk Package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).
2. Suspend container from eyelet support.
3. Remove plastic protector from outlet port at bottom of container.
4. Attach solution transfer set. Refer to complete directions accompanying set.
   Note: The closure shall be penetrated only one time with a suitable sterile transfer device or dispensing set which allows measured dispensing of the contents.
5. The VIAFLEX plastic container should not be written on directly since ink migration has not been investigated. Affix accompanying label for date and time of entry notation.
6. Once container closure has been penetrated, withdrawal of contents should be completed without delay. After initial entry, maintain contents at room temperature (25°C/77°F) and dispense within 4 hours.

2.2 Important Administration Instructions

- Dextrose Injection is *for admixing use only* and is *not for direct intravenous infusion*. Prior to administration, Dextrose Injection *must be diluted* with other compatible intravenous fluids and *used as an admixture* in PN solutions.

- To prevent air embolism, use a non-vented infusion set or close the vent on a vented set, avoid multiple connections, do not connect flexible containers in series, fully evacuate residual gas in the container prior to administration, do not pressurize the flexible container to increase flow rates, and if administration is controlled by a pumping device, turn off pump before the container runs dry.

- When Dextrose Injection is admixed, the choice of a central or peripheral venous route should depend on the osmolarity of the final infusate. Solutions with an osmolarity of 900 mOsm/L or greater must be infused through a central venous catheter *[see Warnings and Precautions (5.4)]*.

- Prior to infusion, visually inspect the PN solution to ensure precipitates have not formed during the mixing or addition of additives. Discard container if precipitates are observed.

- If admixed or infused with lipid emulsion, do not use administration sets and lines that contain di-2-ethylhexyl phthalate (DEHP). Administration sets that contain polyvinyl chloride (PVC) components have DEHP as a plasticizer.

2.3 Dosing Instructions

Caution: Dextrose Injection is *not for direct intravenous infusion.* Prior to administration, Dextrose Injection *must be diluted* with other compatible intravenous fluids or *used as an admixture* in PN solutions.

Dextrose Injection is a part of the parenteral nutrition (PN) regimen which also includes amino acids, electrolytes, and possibly lipid emulsion. Protein, caloric, fluid and electrolyte requirements all need to be taken into consideration when determining individual patient dosage needs.

Individualize the dosage of Dextrose Injection based on the patient's clinical condition (ability to adequately metabolize dextrose), body weight, nutritional and fluid requirements, as well as additional energy given orally or enterally to the patient. Vitamins and trace elements and other components (including amino acids, electrolytes, and lipid emulsion) can be added to the PN solution to meet nutrient needs and prevent deficiencies and complications from developing.

The administration rate should be governed, especially during the first few days of therapy, based on the patient's tolerance to dextrose. Daily intake of amino acids and dextrose should be increased gradually to the maximum required dose as indicated by frequent determinations of blood glucose levels.

In many patients, provision of adequate calories in the form of hypertonic dextrose may require the administration of exogenous insulin to prevent hyperglycemia and glycosuria.

2.4 Discontinuation of Dextrose Injection

To reduce the risk of hypoglycemia, a gradual decrease in flow rate in the last hour of infusion should be considered *[see Warnings and Precautions (5.2), Use in Specific Populations (8.4)]*.

3 DOSAGE FORMS AND STRENGTHS

Dextrose Injection 70%, USP is a sterile, non-pyrogenic, hypertonic solution of 70 grams of dextrose hydrous per 100 mL (0.7 grams/mL) in a 2000 mL Pharmacy Bulk Package flexible container.

4 CONTRAINDICATIONS

The use of Dextrose Injection is contraindicated in patients:

- Who are severely dehydrated as hypertonic dextrose solution can worsen the patient's hyperosmolar state *[see Warnings and Precautions (5.2)]*.
- Known hypersensitivity to dextrose *[see Warnings and Precautions (5.3)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Pulmonary Embolism due to Pulmonary Vascular Precipitates

Pulmonary vascular precipitates causing pulmonary vascular emboli and pulmonary distress have been reported in patients receiving parenteral nutrition. In some cases, fatal outcomes due to pulmonary embolism have occurred. Patients, especially those with hypophosphatemia, may require the addition of phosphate. To prevent hypocalcemia, calcium supplementation should always accompany phosphate administration. Excessive addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates. Precipitates have been reported even in the absence of phosphate salt in the solution. Precipitation following passage through an in-line filter and suspected in vivo precipitate formation has also been reported. If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation. In addition to inspection of the solution *[see Dosage and Administration (2.1, 2.2)]*, the infusion set and catheter should also periodically be checked for precipitates.

5.2 Hyperglycemia and Hyperosmolar Hyperglycemic State

The use of dextrose infusions 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 (5.11)]*. 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. Insulin may be administered or adjusted to maintain optimal blood glucose levels during Dextrose Injection administration.

5.3 Hypersensitivity Reactions

Hypersensitivity and infusion reactions including anaphylaxis have been reported with dextrose injection *[see Adverse Reactions (6)]*. Stop infusion immediately and treat patient accordingly if signs or symptoms of a hypersensitivity reaction develop. Signs or symptoms may include: pruritis, bronchospasm, cyanosis, angioedema, hypotension, pyrexia, chills, and rash.

5.4 Vein Damage and Thrombosis

Dextrose Injection is for admixture with amino acids or dilution with other compatible intravenous fluids. It is not for direct intravenous infusion. Administer solutions with an osmolarity of ≥ 900 mOsm/L through a central vein *[see Dosage and Administration (2.2)]*. The infusion of hypertonic solutions into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis. The primary complication of peripheral access is venous thrombophlebitis, which manifests as pain, erythema, tenderness or a palpable cord. Remove the catheter as soon as possible, if thrombophlebitis develops.

5.5 Hyponatremia

Dextrose Injection is a hypertonic solution *[see Description, Table 1 (11)]*. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization. Monitoring of serum sodium is particularly important for hypotonic fluids.

Depending on the tonicity of the solution, the volume and rate of infusion, and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances, most importantly hypo- or hyperosmotic hyponatremia.

The risk for hyponatremia is increased, in pediatric patients, elderly patients, postoperative patients, those with psychogenic polydipsia and in patients treated with medications that increase the risk of hyponatremia (such as certain diuretic, antiepileptic and psychotropic medications). Close clinical monitoring may be warranted.

Acute hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury. Patients at

increased risk for developing complications of hyponatremia, such as hyponatremic encephalopathy include pediatric patients; women, in particular, premenopausal women; patients with hypoxemia; and in patients with underlying central nervous system disease *[see Use in Specific Populations (8.4)]*.

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

High volume infusion must be used with close monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatremia.

5.6 Risk of Infections

Patients who require parenteral nutrition are at high risk of infections because the nutritional components of these solutions can support microbial growth. Infection and sepsis may also occur as a result of the use of intravenous catheters to administer parenteral nutrition.

The risk of infection is increased in patients with malnutrition-associated immunosuppression, hyperglycemia exacerbated by dextrose infusion, long-term use and poor maintenance of intravenous catheters, or immunosuppressive effects of other concomitant conditions, drugs, or other components of the parenteral formulation (e.g., lipid emulsion).

To decrease the risk of infectious complications, ensure aseptic technique in catheter placement and maintenance, as well as aseptic technique in the preparation and administration of the nutritional formula.

Monitor for signs and symptoms (including fever and chills) of early infections, including laboratory test results (including leukocytosis and hyperglycemia) and frequent checks of the parenteral access device and insertion site for edema, redness and discharge.

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 intakes including Dextrose Injection.

5.8 Hepatobiliary Disorders

Hepatobiliary disorders are known to develop in some patients without preexisting liver disease who receive parenteral nutrition, including cholecystitis, cholelithiasis, cholestasis, hepatic steatosis, fibrosis and cirrhosis, possibly leading to hepatic failure. The etiology of these disorders is thought to be multifactorial and may differ between patients.

Monitor liver function parameters and ammonia levels. Patients developing signs of hepatobiliary disorders should be assessed early by a clinician knowledgeable in liver diseases in order to identify possible causative and contributory factors, and possible therapeutic and prophylactic interventions.

5.9 Aluminum Toxicity

Dextrose Injection contains no more than 25 mcg/L of aluminum. However, with prolonged parenteral administration in patients with renal impairment, the aluminum contained in Dextrose Injection may reach toxic levels. Preterm infants are at greater risk because their kidneys are immature, and they require large amounts of concomitant calcium and phosphate solutions that contain aluminum. Patients with renal impairment, including preterm infants, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day, accumulate aluminum at levels associated with central nervous system (CNS) and bone toxicity. Tissue loading may occur at even lower rates of administration of total parenteral nutrition products *[see Use in Specific Populations (8.4)]*.

5.10 Risk of Parenteral Nutrition Associated Liver Disease

Parenteral Nutrition Associated Liver Disease (PNALD) has been reported in patients who receive parenteral nutrition for extended periods of time, especially preterm infants, and can present as cholestasis or steatohepatitis. The exact etiology is not entirely clear and is likely multifactorial. If Dextrose Injection-treated patients develop abnormal liver function tests, consider discontinuation or dosage reduction.

5.11 Electrolyte Imbalance and Fluid Overload

Electrolyte deficits, particularly in serum potassium and phosphate, may occur during prolonged use of concentrated dextrose solutions.

Depending on the volume and rate of infusion, the intravenous administration of concentrated dextrose solutions can cause fluid and/or solute overloading resulting in

dilution of serum electrolyte concentrations (including hypoosmotic hyponatremia), overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations in the administered solution. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations in the solution.

Monitor blood electrolyte levels, glucose, acid-base balance, correct fluid and electrolyte imbalances, and administer essential vitamins and minerals as needed. Monitor daily fluid balance. Additional monitoring is recommended for patients with water and electrolyte disturbances that could be aggravated by increased glucose and/or free water load. Patients at increased risk for developing hyponatremic encephalopathy include pediatric patients; elderly patients, women, in particular premenopausal women; patients with hypoxemia; and patients with underlying CNS disease *[see Use in Specific Populations (8.4, 8.5)]*.

6 ADVERSE REACTIONS

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.

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

- Pulmonary embolism due to pulmonary vascular precipitates *[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)]*
- Vein damage and thrombosis *[see Warnings and Precautions (5.4)]*
- *H*yponatremia and hyponatremic encephalopathy *[see Warnings and Precautions (5.5)]*
- Risk of infections *[see Warnings and Precautions (5.6)]*
- Refeeding syndrome *[see Warnings and Precautions (5.7)]*
- Aluminum toxicity *[see Warnings and Precautions (5.9)]*

- Hepatobiliary disorders *[see Warnings and Precautions (5.8)]*
- Risk of parenteral nutrition associated liver disease *[see Warnings and Precautions (5.10)]*
- Electrolyte imbalance and fluid overload *[see Warnings and Precautions (5.11)]*

7 DRUG INTERACTIONS

7.1 Other Products that Affect Glycemic Control or Fluid and/or Electrolyte Balance

Dextrose Injection can affect glycemic control and fluid and/or electrolyte balance *[see Warnings and Precautions (5.2, 5.5, 5.11)]*. Monitor blood glucose concentrations, fluid balance, serum electrolyte concentrations and acid-base balance when using Dextrose Injection in patients treated with other substances that affect glycemic control, or fluid and/or electrolyte balance (such as diuretics and anti-epileptics).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Appropriate administration of Dextrose Injection during pregnancy is not expected to cause adverse developmental outcomes, including congenital malformations. However, maternal hyperglycemia secondary to infusion of glucose-containing products at the time of delivery has been associated with adverse neonatal outcomes such as neonatal hypoglycemia. Malnutrition in pregnant women is associated with adverse maternal and fetal outcomes *(see Clinical Considerations).* Animal reproduction studies have not been conducted with injectable dextrose solutions.

The estimated 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.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Severe malnutrition in pregnant women is associated with preterm delivery, low birth weight, intrauterine growth restriction, congenital malformations and perinatal mortality. Parenteral nutrition should be considered if a pregnant woman’s nutritional requirements cannot be fulfilled by oral or enteral intake.

8.2 Lactation

Risk Summary

There are no data on the presence of dextrose in human milk, the effects on a breastfed infant, or the effects on milk production. The lack of clinical data during lactation precludes a clear determination of the risk of Dextrose Injection to an infant during lactation; therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Dextrose Injection and any potential adverse effects on the breastfed infant from Dextrose Injection or from the underlying maternal condition.

8.4 Pediatric Use

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

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

Plasma electrolyte concentrations should be closely monitored in pediatric patients who may have impaired ability to regulate fluids and electrolytes. In very low birth weight infants, excessive or rapid administration of Dextrose Injection may result in increased serum osmolality and risk of intracerebral hemorrhage.

Because of immature renal function, preterm infants receiving prolonged treatment with dextrose injection, may be at risk of aluminum toxicity *[see Warnings and Precautions (5.9)]*. Patients, including pediatric patients, may be at risk for Parenteral Nutrition Associated Liver Disease (PNALD) *[see Warnings and Precautions (5.10)]*.

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

8.5 Geriatric Use

Clinical studies of Dextrose Injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Elderly 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 elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of

decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

10 OVERDOSAGE

An increased infusion rate of Dextrose Injection or administration of a concentrated dextrose solution can cause hyperglycemia, hyperosmolality, and adverse effects on water and electrolyte balance *[see Warnings and Precautions (5.2, 5.11)]*.

Severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal. Discontinue infusion and institute appropriate corrective measures such as administration of exogenous insulin.

Discontinue infusion and institute appropriate corrective measures in the event of overhydration or solute overload during therapy, with particular attention to CNS, respiratory and cardiovascular systems.

If over-exposure occurs, call your Poison Control Center at 1-800-222-1222 for current information on the management of poisoning or overdosage.

11 DESCRIPTION

Dextrose Injection 70%, USP is a clear, sterile, nonpyrogenic, hypertonic solution of Dextrose, USP in Water for Injection in a flexible plastic container as a Pharmacy Bulk Package. A Pharmacy Bulk Package is a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program. Dextrose Injection is *not for direct intravenous infusion [see Dosage and Administration (2.1)]*.

The Pharmacy Bulk Package is designed to facilitate admixture or dilution to provide dextrose in various concentrations and is available in a 2000 mL size. 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 following admixture or dilution. The pH range is 4.0 (3.2 to 6.5).

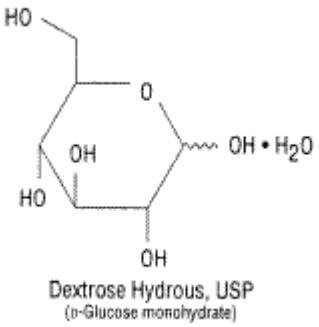
Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly.

Table 1. Contents and Characteristics of Dextrose Injection 70%, USP

Strength	Fill Volume	Amount of Dextrose Hydrous, USP per container	kcal* per Container	Osmolarity (mOsmol per liter) (calc.)
Dextrose Injection 70%, USP (0.7 grams/mL)	2000 mL	1400 grams	4760	3530

*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 Injection 70%, USP contains no more than 25 mcg/L of aluminum.

Dextrose is derived from corn.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Dextrose Injection is used to supplement nutrition by providing glucose parenterally. Dextrose is oxidized to carbon dioxide and water, yielding energy.

16 HOW SUPPLIED/STORAGE AND HANDLING

Dextrose Injection 70%, USP (0.7 grams/mL) is available in a Pharmacy Bulk Package flexible plastic container for intravenous administration after appropriate dilution *[see Dosage and Administration (2.1)]* and is available in the following size in **Table 2** below.

Table 2

Product Description	Code	Volume	NDC
Dextrose Injection 70%, USP (0.7 grams/mL)	2B0296	2000 mL	0338-0719-06

Do not remove container from the overwrap until ready to use.

Store at room temperature (25°C /77°F).

Do not freeze.

Avoid excessive heat.

For storage of admixed solution, see *Dosage and Administration (2.1).*

17 PATIENT COUNSELING INFORMATION

Inform patients, caregivers, or home healthcare providers of the following risks of Dextrose Injection:

- Pulmonary embolism due to pulmonary vascular precipitates *[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)]*
- Vein damage and thrombosis *[see Warnings and Precautions (5.4)]*
- Hyponatremia *[see Warnings and Precautions (5.5)]*
- Risk of infections *[see Warnings and Precautions (5.6)]*
- Refeeding syndrome *[see Warnings and Precautions (5.7)]*
- Hepatobiliary disorders *[see Warnings and Precautions (5.8)]*
- Aluminum toxicity *[see Warnings and Precautions (5.9)]*
- Risk of parenteral nutrition associated liver disease *[see Warnings and Precautions (5.10)]*

- Electrolyte imbalance and fluid overload *[see Warnings and Precautions (5.11)]*

Manufactured by, Packed by, Distributed by:

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

07-19-73-116

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

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

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

Contraindications (4)	08/2019
Warnings and Precautions (5.1, 5.2, 5.3, 5.4, 5.5, 5.6)	08/2019

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

Dextrose Injection is indicated as a source of calories and water and may also be used as diluent for reconstitution of a powdered or liquid (up to 10 mL) drug product packaged in a vial with a 20 mm closure. (1)

----------DOSAGE AND ADMINISTRATION----------

- Only for intravenous infusion. (2.1)
- See full prescribing information for information on preparation, administration, dosing considerations and instructions for use. (2.1, 2.2, 2.3)

----------DOSAGE FORMS AND STRENGTHS----------

Injection: 5% (0.05 grams/mL), 5 grams of dextrose hydrous per 100 mL in 50 mL and 100 mL single-dose, partial-fill flexible containers: (3)

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

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

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

- Hyperglycemia or Hyperosmolar Hyperglycemic State: Monitor blood glucose and administer insulin as needed. (5.1)
- Hypersensitivity Reactions: Monitor for signs and symptoms and discontinue infusion if reactions occur. (5.2)
- Vein Damage and Thrombosis: Consider central vein when administering more than 5% dextrose or with an osmolarity of ≥ 900 mOsm/L or when there is peripheral vein irritation, phlebitis, and/or associated pain. (2.2, 5.3)
- Hyponatremia: Avoid in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations (5.4)
- Electrolyte Imbalance and Fluid Overload: Avoid in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor daily fluid balance, electrolyte concentrations, and acid-base balance, as needed and especially during prolonged use (5.5)
- Refeeding Syndrome: Monitor severely undernourished patients and slowly increase nutrient intake. (5.6)

----------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 ----------

Other Products that Affect Glycemic Control, Vasopressin or Fluid and/or Electrolyte Balance: Monitor blood glucose concentrations, fluid balance, serum electrolyte concentrations and acid-base balance. (7.1)

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

Pediatric Use: Increased risk of hypoglycemia/hyperglycemia; monitor serum glucose concentrations. (8.4)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 08/2019

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Dextrose Injection is indicated as source of water and calories and may also be used as diluent for reconstitution of a powdered or liquid (up to 10 mL) drug product packaged in a vial with a 20 mm closure.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

- Dextrose Injection is intended for intravenous use.
- Peripheral administration of 5% dextrose is generally acceptable, however, consider central vein when administering more than 5% dextrose or with an osmolarity of at least 900 mOsm/L or when there is peripheral vein irritation, phlebitis, and/or associated pain *[see Warnings and Precautions (5.3)]*.
- Do not administer Dextrose Injection simultaneously with blood products through the same administration set because of the possibility of pseudoagglutination or hemolysis.
- To prevent air embolism, use a non-vented infusion set or close the vent on a vented set, avoid multiple connections, do not connect flexible containers in series, fully evacuate residual gas in the container prior to administration, do not pressurize the flexible container to increase flow rates, and if administration is controlled by a pumping device, turn off pump before the container runs dry.
- Prior to infusion, visually inspect the diluted dextrose solution for particulate matter. The solution should be clear and there should be no precipitates. Do not administer unless solution is clear and container is undamaged.
- Use of a final filter is recommended during administration of parenteral solutions, where possible.

2.2 Recommended Dosage

The choice of dextrose concentration, 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 premature infants 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)]*.

2.3 Instructions for Use

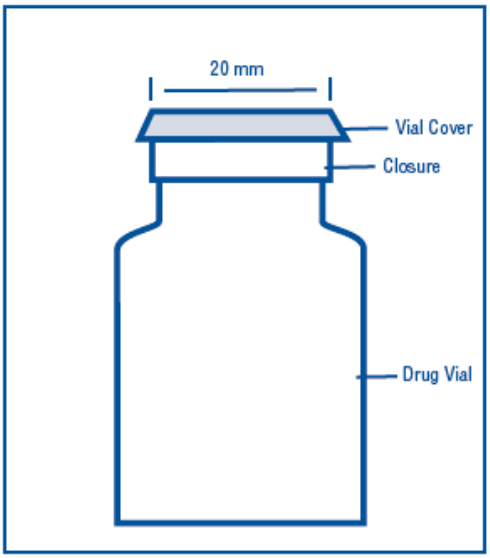
To Open

- Do not remove from overpouch until ready to use.
- Tear overwrap sharply down from the 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 separately squeezing the inner bag firmly. If leaks are found, discard container.
    - Check that the vial adaptor cover is intact. If the vial adaptor cover is not intact, discard product.

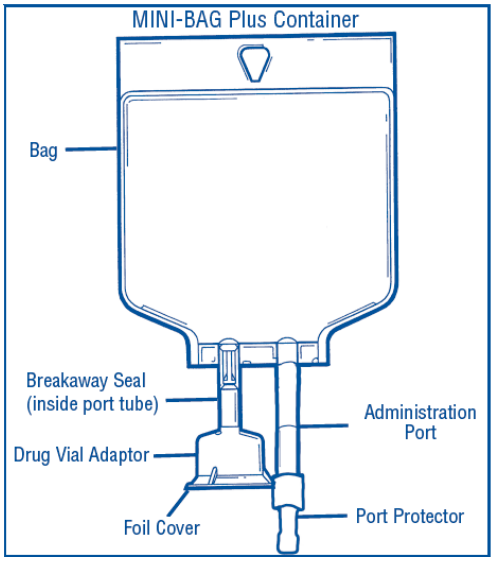
Preparation for Administration

- Instructions for Assembly and Reconstitution: (Steps 1-3 for Assembly and steps 4-6 for Reconstitution)

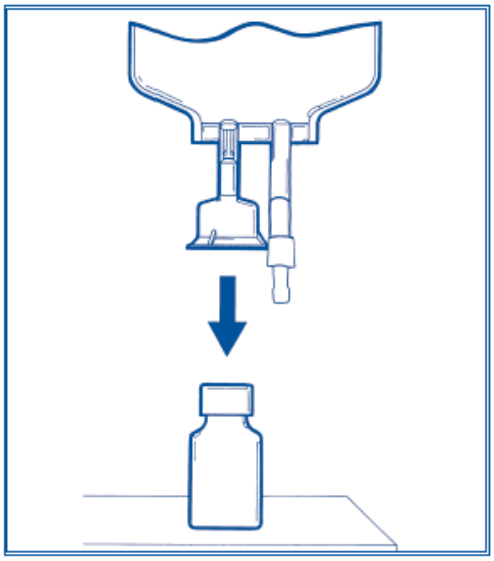
    Step 1: Remove vial cover and disinfect stopper.



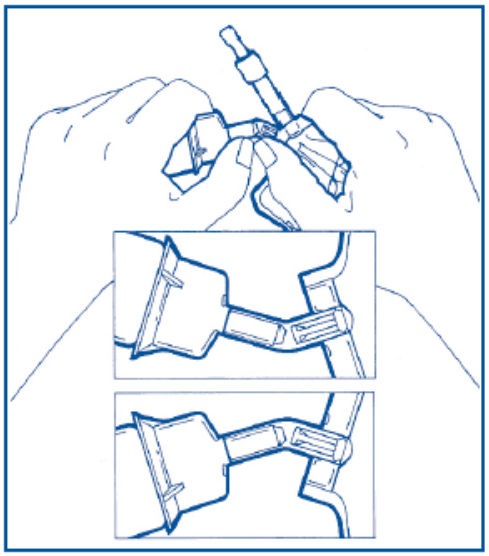
Step 2: Peel off foil cover. Inspect adaptor for moisture. Discard if moisture is found.



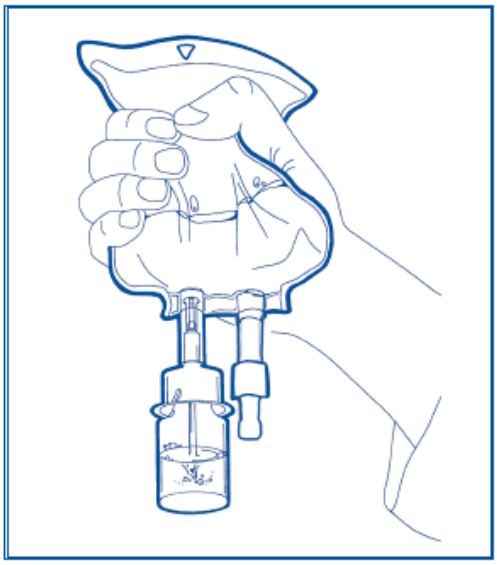
Step 3: Place vial upright and hold firmly. Push adaptor down until vial snaps in place. DO NOT TWIST. Pull vial to ensure fully seated.



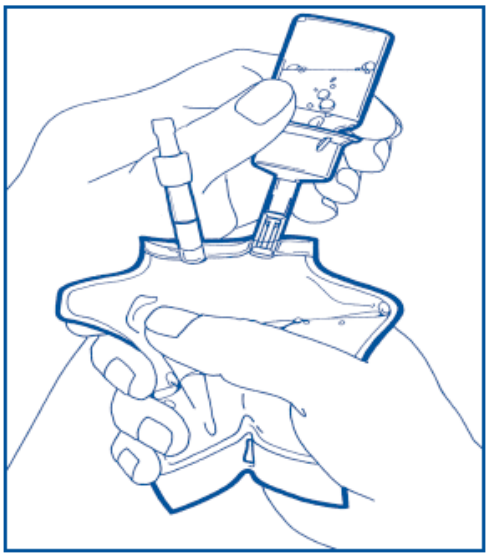
Step 4: Squeeze the bag and check vial. Use only if vial is fully seated and dry. Bend up then down to break the seal.



Step 5: Hold bag with vial down. Squeeze solution into vial until half full. Shake to suspend drug in solution.



Step 6: Hold bag with vial upside down. Squeeze bag to force air into vial. Release to drain suspended drug from vial. Repeat *steps 5 and 6* until vial is empty of drug and solution is thoroughly mixed. Ensure drug is completely dissolved. Do Not Remove Drug Vial.



- Inspect the container to ensure precipitates have not formed during the mixing or addition of additives and that the solution has not changed color. Discard the admixture if either are observed.
- Insert transfer set into prepared solution container to be transferred. Follow directions accompanying transfer set.

- Remove port protector and attached administration set per its directions.
- Transfer solution by gravity. Ensure that vial is empty of drug and solution. Repeat step 6 if drug and solution remain in vial.
- Check for leaks.

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.

Storage

- Use promptly after admixing or dilution; do not store solutions containing additives.
- Single-dose container.
- Discard unused portion.

3 DOSAGE FORMS AND STRENGTHS

Dextrose Injection, USP is a clear, sterile, non-pyrogenic solution of 5 grams of dextrose hydrous per 100 mL (0.05 grams/mL) in 50 mL and 100 mL single-dose, partial-fill flexible containers.

4 CONTRAINDICATIONS

The use of Dextrose Injection is contraindicated in patients with:

- Clinically significant hyperglycemia *[see Warnings and Precautions (5.1)]*.
- Known hypersensitivity to dextrose *[see Warnings and Precautions (5.2)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Hyperglycemia and Hyperosmolar Hyperglycemic State

The use of dextrose infusions 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 (5.5)]*. 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. Insulin may be administered or adjusted to maintain optimal blood glucose levels during Dextrose Injection administration.

5.2 Hypersensitivity Reactions

Hypersensitivity and infusion reactions including anaphylaxis, have been reported with Dextrose Injection *[see Adverse Reactions (6)]*. Stop infusion immediately and treat patient accordingly if signs or symptoms of a hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

5.3 Vein Damage and Thrombosis

Peripheral administration of 5% Dextrose Injection is generally acceptable, however, consider central vein when administering more than 5% dextrose or with an osmolarity of ≥ 900 mOsm/L or when there is peripheral vein irritation, phlebitis, and/or associated pain *[see Dosage and Administration (2.1)]*. The infusion of hypertonic solutions into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis. The primary complication of peripheral access is venous thrombophlebitis, which manifests as pain, erythema, tenderness or a palpable cord. Remove the catheter as soon as possible, if thrombophlebitis develops.

5.4 Hyponatremia

5% Dextrose Injection is an isotonic solution *[see Description, Table 1 (11)]*. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization. Monitoring of serum sodium is particularly important for hypotonic fluids.

Depending on the tonicity of the solution, the volume and rate of infusion, and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances, most importantly hypo- or hyperosmotic hyponatremia. Monitor serum sodium to minimize the risk of hyponatremia.

The risk for hyponatremia is increased in pediatric patients, elderly patients, postoperative patients, those with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (such as diuretics, certain antiepileptic and psychotropic medications). Close clinical monitoring may be warranted.

Acute hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury. Patients at increased risk for developing complications of hyponatremia, such as hyponatremic encephalopathy include pediatric patients; women, in particular, premenopausal women; patients with hypoxemia; and in patients with underlying central nervous system disease *[see Use in Specific Populations (8.4, 8.5)]*.

Avoid Dextrose Injection in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations.

Rapid correction of hyponatremia is potentially dangerous with risk of serious neurologic complications. Brain adaptations reducing risk of cerebral edema make the brain vulnerable to injury when chronic hyponatremia is too rapidly corrected, which is known as osmotic demyelination syndrome (ODS). To avoid complications, monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and signs of neurologic complications.

High volume infusion must be used with close monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatremia

5.5 Electrolyte Imbalance and Fluid Overload

Electrolyte deficits, particularly in serum potassium and phosphate, may occur during prolonged use of concentrated dextrose solutions.

Depending on the volume and rate of infusion, the intravenous administration of dextrose solutions can cause fluid and/or solute overloading resulting in dilution of serum

electrolyte concentrations (including hypoosmotic hyponatremia, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations in the administered solution. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations in the solution.

Avoid Dextrose Injection in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor fluid balance, blood electrolyte levels, concentration of glucose, acid-base balance, correct fluid and electrolyte imbalances during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation. 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.

Patients at increased risk for developing hyponatremic encephalopathy include pediatric patients; elderly patients, women, in particular premenopausal women; patients with hypoxemia; and patients with underlying CNS disease *[see Use in Specific Populations (8.4, 8.5)]*.

5.6 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 intakes.

6 ADVERSE REACTIONS

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.

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

- Hyperglycemia and hyperosmolar hyperglycemic state *[see Warnings and Precautions (5.1)]*

- Hypersensitivity reactions: anaphylaxis, pruritis, bronchospasm, cyanosis, angioedema, hypotension, pyrexia, chills, and rash *[see Warnings and Precautions (5.2)]*
- Infusion Site Reactions: infusion site phlebitis, infusion site erythema, vein damage and thrombosis *[see Warnings and Precautions (5.3)]*
- Hyponatremia and hyponatremic encephalopathy *[see Warnings and Precautions (5.4)]*
- Refeeding syndrome *[see Warnings and Precautions (5.6)]*
- Electrolyte imbalance, fluid overload and hypervolemia *[see Warnings and Precautions (5.5)]*

7 DRUG INTERACTIONS

7.1 Other Products that Affect Glycemic Control or Fluid and/or Electrolyte Balance

Dextrose Injection can affect glycemic control, vasopressin and fluid and/or electrolyte balance *[see Warnings and Precautions (5.1, 5.4, 5.5)]*. Monitor blood glucose concentrations, fluid balance, serum electrolyte concentrations and acid-base balance when using Dextrose Injection in patients treated with other substances that affect glycemic control, vasopressin or fluid and/or electrolyte balance.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Appropriate administration of Dextrose Injection during pregnancy is not expected to cause adverse developmental outcomes, including congenital malformations. Animal reproduction studies have not been conducted with injectable dextrose solutions.

The estimated 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

There are no data on the presence of dextrose in human milk, the effects on a breastfed infant, or the effects on milk production. The lack of clinical data during lactation precludes a clear determination of the risk of Dextrose Injection to an infant during lactation; therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Dextrose Injection and any potential adverse effects on the breastfed infant from Dextrose Injection or from the underlying maternal condition.

8.4 Pediatric Use

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

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

Closely monitor plasma electrolyte concentrations in pediatric patients who may have impaired ability to regulate fluids and electrolytes. In very low birth weight infants, excessive or rapid administration of Dextrose Injection may result in increased serum osmolality and risk of intracerebral hemorrhage.

Children (including neonates and older children) are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy *[see Warnings and Precautions (5.4)]*.

8.5 Geriatric Use

Clinical studies of Dextrose Injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Elderly patients are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy *[see Warnings and Precautions (5.4)]*. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Dextrose is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

10 OVERDOSAGE

An increased infusion rate of Dextrose Injection or administration of dextrose solutions can cause hyperglycemia, hyperosmolality, and adverse effects on water and electrolyte balance *[see Warnings and Precautions (5.1, 5.5)]*.

Severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal. Discontinue infusion, reduce dose and institute appropriate corrective measures such as administration of exogenous insulin.

Discontinue infusion and institute appropriate corrective measures in the event of overhydration or solute overload during therapy, with particular attention to CNS, respiratory and cardiovascular systems.

If over-exposure occurs, call your Poison Control Center at 1-800-222-1222 for current information on the management of poisoning or overdosage.

11 DESCRIPTION

Dextrose Injection, 5% USP is a clear, sterile, non-pyrogenicsolutions of Dextrose, USP in Water for Injection in a polyvinylchloride flexible plastic container for intravenous administration after admixture with a single dose powdered or liquid (up to 10 mL) drug vial *[see Dosage and Administration (2.1)]*.

Partial-fill containers, designed to facilitate admixture, are available in 50 mL, and 100 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).

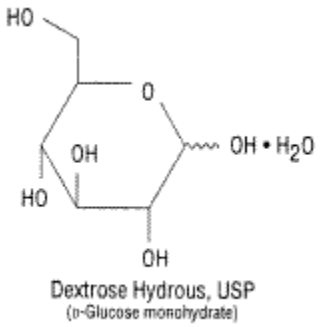
Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly.

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

Strength	Fill Volume	Amount of Dextrose Hydrous per Container	kcal* per Container	mOsmol per liter
Dextrose Injection 5%, USP (0.05 grams/mL)	50 mL	2.5 grams	8.5	252
	100 mL	5 grams	17	252

*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:



Dextrose Hydrous, USP
(D-Glucose monohydrate)

Water for Injection, USP is chemically designated H_2O.

Dextrose is derived from corn.

The MINI-BAG Plus Container is a standard diluent container with an integral drug vial adaptor. It allows for drug admixture after connection to a single dose powdered or liquid (up to 10 mL) drug vial having a 20 mm closure. A breakaway seal in the tube between the vial adaptor and the container is broken to allow transfer of the diluent into the vial and reconstitution of the drug. The reconstituted drug is then transferred from the vial into the container diluent and mixed to result in an admixture for delivery to the patient.

The VIAFLEX Plus plastic container is fabricated from a specially formulated 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 significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, 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 oxidized to carbon dioxide and water, yielding energy.

16 HOW SUPPLIED/STORAGE AND HANDLING

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

Product Description	Size	Code	NDC
Dextrose Injection 5%, USP (0.05 grams/mL)	50 mL	2B0040	0338-0551-11
	100 mL	2B0041	0338-0551-18

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

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

Store between 20ºC to 25°C (68º F to 77°F). [See USP controlled room temperature.]

Do not freeze.

17 PATIENT COUNSELING INFORMATION

Inform patients, caregivers, or home healthcare providers of the following risks of Dextrose Injection:

- Hyperglycemia and hyperosmolar hyperglycemic state *[see Warnings and Precautions (5.1)]*
- Hypersensitivity reactions *[see Warnings and Precautions (5.2)]*
- Vein damage and thrombosis *[see Warnings and Precautions (5.3)]*
- Hyponatremia *[see Warnings and Precautions (5.4)]*
- Electrolyte imbalance and fluid overload *[see Warnings and Precautions (5.5)]*
- Refeeding syndrome *[see Warnings and Precautions (5.6)]*

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