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

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

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

Dosage and Administration (2.1, 2.2, 2.3)	06/2025
Contraindications (4)	06/2025
Warnings and Precautions (5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7)	06/2025

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

Dextrose Injection (5%) is indicated as a source of water and calories in adult and pediatric patients and may also be used as a diluent for reconstitution of a powder or liquid drug product. (1)

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

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

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

Injection:

- 5% (5 g/100 mL) (50 mg/mL) of dextrose hydrous in single-dose flexible plastic ADD-Vantage™ diluent containers: 50 mL, 100 mL and 250 mL.

This dextrose product is intended to be used as a diluent for the contents of an ADD-Vantage vial or a single-dose powdered drug vial with 20 mm closure using the ADD-Vantage ADDAPTOR™. (3)

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

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

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

- Neonatal Hypoglycemia: Closely monitor blood glucose concentration to ensure adequate glycemic control. (5.1)
- Hyperglycemia and Hyperosmolar Hyperglycemic State: Use with caution in patients with known subclinical or overt diabetes mellitus. (5.2)
- Hypersensitivity Reactions: Monitor for signs and symptoms and discontinue infusion immediately if reaction occurs. (5.3)
- Phlebitis and Thrombosis: Remove catheter as soon as possible if thrombophlebitis develops. (2.1, 5.4)
- Hyponatremia: Monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and neurologic status. (5.5)
- Electrolyte Imbalance and Fluid Overload: Monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during administration. (5.6)
- Refeeding Syndrome: Monitory 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, phlebitis, and electrolyte imbalance. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer, Inc. at 1-800-438-1985 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: 06/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

Dextrose Injection (5%) is intended for intravenous use.

- Use a peripheral vein to administer if the final dextrose concentration is 5% or less and the osmolarity is less than 900 mOsm/L.
- To avoid venous irritation, consider using a central vein to administer hypertonic solutions with osmolarity of 900 mOsm/L or greater *[see Warnings and Precautions (5.4)]*.
- Do not administer Dextrose Injection (5%) simultaneously with blood products through the same administration set because of the possibility of pseudoagglutination or hemolysis.
- Use of a final filter is recommended during administration of parenteral solutions, where possible.
- Discard the unused portion.
- Do not use the Dextrose Injection (5%) ADD-Vantage™ diluent containers with chemotherapy agents**.**

2.2 Important Preparation Information

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

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

- Use a non-vented infusion set or close the vent on a vented set.
- Use a dedicated line without any connections (do not connect flexible containers in series).
- Do **not** pressurize the flexible container to increase flow rates.
- If using a pumping device to administer Dextrose Injection (5%), turn off the pump before the container is empty.

To Open:

- Peel overwrap at corner and remove solution container.
  - Use unit within 30 days of opening overwrap, as long as the use date does not exceed the printed expiration date.
- 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.

To Assemble Vial and Flexible Diluent Container:

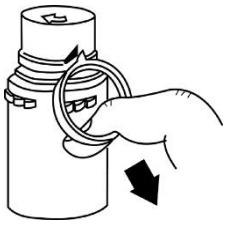


Fig. 1

Fig. 2

1. Remove the protective covers from the top of the vial and the vial port on the diluent container as follows:

    a. To remove the breakaway vial cap, swing the pull ring over the top of the vial and pull down far enough to start the opening (SEE FIGURE 1.), then pull straight up to remove the cap. (SEE FIGURE 2.)

NOTE: Once the breakaway cap has been removed, do not access the vial with the syringe.

    b. To remove the vial port cover, grasp the tab on the pull ring, pull up to break the three tie strings, then pull back to remove the cover. (SEE FIGURE 3.)

Fig. 3

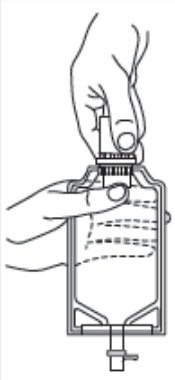


Fig. 4

2. Screw the vial into the vial port until it will go no further. THE VIAL MUST BE SCREWED IN TIGHTLY TO ASSURE A SEAL. This occurs approximately 1/2 turn (180°) after the first audible click. (SEE FIGURE 4.) The clicking sound does not assure a seal; the vial must be turned as far as it will go.

NOTE: Once vial is seated, do not attempt to remove. (SEE FIGURE 4.)

3. Recheck the vial to assure that it is tight by trying to turn it further in the direction of assembly.

4. Label appropriately.

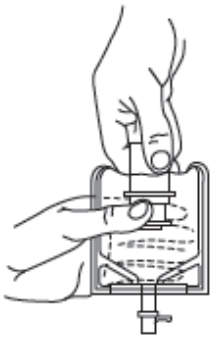


Fig 5

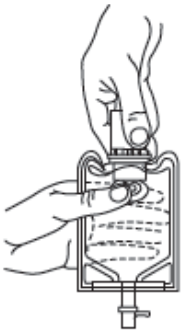


Fig 6

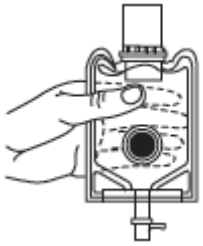


Fig 7

To Reconstitute the Drug:

1. Squeeze the bottom of the diluent container gently to inflate the portion of the container surrounding the end of the drug vial.
2. With the other hand, push the drug vial down into the container telescoping the walls of the container. Grasp the inner cap of the vial through the walls of the container. (SEE FIGURE 5.)
3. **Pull the inner cap from the drug vial. (SEE FIGURE 6.) Verify that the rubber stopper has been pulled out, allowing the drug and diluent to mix.**
4. Mix container contents thoroughly and use within the specified time.
5. Look through the bottom of the vial to verify that the stopper has been removed and complete mixing has occurred. (SEE FIGURE 7.)

If the rubber stopper is not removed from the vial, and the medication is not released on the first attempt, the inner cap may be manipulated back into the rubber stopper without removing the drug vial from the diluent container. Repeat steps 3 through 5.

Preparation for Administration:

1. Confirm the activation and admixture of vial contents.
2. Check for leaks by squeezing the container firmly. If leaks are found, discard the unit because sterility may be compromised.
3. Close the flow control clamp of the administration set.
4. Remove the cover from the outlet port at the bottom of the container.
5. Insert the piercing pin of the administration set into the port with a twisting motion until the pin is firmly seated. **Note:** See full directions on the administration set carton.
6. Lift the free end of the hanger loop on the bottom of the vial, breaking the two tie strings. Bend the loop outward to lock it in the upright position, then suspend the container from the hanger.
7. Squeeze and release the drip chamber to establish the proper fluid level in the chamber.
8. Open the flow control clamp and clear air from set. Close clamp.
9. Attach the set to the venipuncture device. If the device is not indwelling, prime and make venipuncture.
10. Regulate the rate of administration with the flow control clamp. **Do not use the flexible container in series connections.**

2.3 Dosage Considerations

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

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

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

3 DOSAGE FORMS AND STRENGTHS

Injection:

- 5% (5 g/100 mL) (50 mg/mL) of dextrose hydrous in a clear, sterile, and nonpyrogenic solution in single-dose flexible plastic ADD-Vantage™ diluent containers: 50 mL, 100 mL and 250 mL.

This dextrose product is intended to be used as a diluent for the contents of an ADD-Vantage vial or a single-dose powdered drug vial with 20 mm closure using the ADD-Vantage ADDAPTOR™.

4 CONTRAINDICATIONS

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

- Clinically significant hyperglycemia *[see Warnings and Precautions (5.2)]*.
- Known hypersensitivity to dextrose *[see Warnings and Precautions (5.3)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Neonatal Hypoglycemia

Neonates, especially preterm neonates with low birth weight, are at increased risk of developing hypoglycemia. Closely monitor blood glucose concentration during treatment with Dextrose Injection (5%) to ensure adequate glycemic control in order to avoid potential long-term adverse effects.

5.2 Hyperglycemia and Hyperosmolar Hyperglycemic State

The use of Dextrose Injection (5%) in patients with impaired glucose tolerance may worsen hyperglycemia. Administration of dextrose at a rate exceeding the patient's utilization rate may lead to hyperglycemia, coma, and death.

Hyperglycemia is associated with an increase in serum osmolality, resulting in osmotic diuresis, dehydration, and electrolyte losses *[see Warnings and Precautions (5.6), Use in Specific Populations (8.4)]*. Patients with underlying CNS disease and renal impairment who receive dextrose infusions may be at greater risk of developing hyperosmolar hyperglycemic state.

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

5.3 Hypersensitivity Reactions

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

5.4 Phlebitis and Thrombosis

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

5.5 Hyponatremia

Dextrose Injection (5%) may cause hyponatremia. Hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy, and vomiting. The risk of hospital-acquired hyponatremia is increased in younger pediatric patients, geriatric patients, patients treated with diuretics, and patients with cardiac or pulmonary failure or with the syndrome of inappropriate antidiuretic hormone (SIADH) (e.g., postoperative patients, patients concomitantly treated with arginine vasopressin analogs or certain antiepileptic, psychotropic, and cytotoxic drugs) *[see Drug Interactions (7.1), Use in Specific Populations (8.4)]*.

Avoid Dextrose Injection (5%) in patients with or at risk for hyponatremia. If use cannot be avoided, closely monitor serum sodium concentrations, chloride concentrations, fluid status, acid-base balance, and neurologic status *[see Warnings and Precautions (5.6)]*.

5.6 Electrolyte Imbalance and Fluid Overload

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

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

Avoid Dextrose Injection (5%) in patients at risk for fluid and/or solute overload. If use cannot be avoided in these patients, monitor fluid balance, electrolyte concentrations, and acid-base balance, especially during prolonged use. Additional monitoring is recommended for patients with water and electrolyte disturbances that could be aggravated by increased glucose, insulin administration, and/or free water load.

5.7 Refeeding Syndrome

Refeeding severely undernourished patients may result in refeeding syndrome, characterized by the intracellular shift of potassium, phosphorus, and magnesium as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. To prevent these complications, monitor severely undernourished patients and slowly increase nutrient intake.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are also 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, Fluid Overload and Hypervolemia *[see Warnings and Precautions (5.6)]*
- Refeeding Syndrome *[see Warnings and Precautions (5.7)]*

The following adverse reactions associated with the use of Dextrose Injection (5%) were identified in clinical trials or postmarketing reports. Because some of these reactions were reported voluntarily from a population of

uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

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

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

Cardiovascular disorders: cyanosis, volume overload

7 DRUG INTERACTIONS

7.1 Drugs with Effects on Glycemic Control and Electrolyte Balance

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

Concomitant administration of Dextrose Injection (5%) with drugs associated with hyponatremia may increase the risk of developing hyponatremia. Drugs associated with hyponatremia include diuretics and those that cause SIADH (e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), arginine vasopressin analogs, certain antiepileptic, psychotropic, and cytotoxic drugs). Avoid use of Dextrose Injection (5%) in patients receiving drugs associated with hyponatremia. If use cannot be avoided, closely monitor serum sodium concentrations during concomitant use *[see Warnings and Precautions (5.5)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Dextrose Injection (5%) has been used for decades during labor and delivery. Although there are a few case reports that describe adverse effects of dextrose use in other stages of pregnancy, exposure during pregnancy in general is not expected to cause major birth defects, miscarriage, or adverse maternal or fetal outcomes. Animal reproduction studies have not been conducted with dextrose.

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

8.2 Lactation

Risk Summary

Dextrose Injection (5%) has been used for decades and is not expected to cause harm to a breastfed infant. There are no data on the effects of Dextrose Injection (5%) on levels of glucose in human milk, on the breastfed infant, or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Dextrose Injection (5%) and any potential adverse effects on the breastfed infant from Dextrose Injection (5%) or from the underlying maternal condition.

8.4 Pediatric Use

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

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

Dextrose Injection (5%) can cause imbalances in fluid and electrolytes in pediatric patients and requires close monitoring of volume status and plasma electrolyte concentrations, particularly in pediatric patients who may have impaired ability to regulate fluids and electrolytes. Pediatric patients are at increased risk for developing hyponatremic encephalopathy *[see Warnings and Precautions (5.5, 5.6)]*.

In very low birth weight neonates, excessive or rapid administration of Dextrose Injection (5%) may increase the risk of intracerebral hemorrhage.

8.5 Geriatric Use

Dextrose Injection (5%) has not been studied in sufficient number of patients aged 65 and over to determine whether they respond differently from younger patients. Geriatric patients are at increased risk of developing hyponatremia and hyponatremic encephalopathy *[see Warnings and Precautions (5.5)]*. Other reported clinical experience has not identified differences in responses between the geriatric and younger adult patients. In general, the infusion rate for geriatric patients should start slow and be titrated up cautiously, reflecting their greater risk for electrolyte abnormalities and fluid overload.

Dextrose is known to be substantially excreted by the kidney, and the risk of adverse reactions to Dextrose Injection (5%) may be greater in patients with impaired renal function. Because geriatric patients are more likely to have impaired renal function, care should be taken in selection of the infusion rate, and patients should be closely monitored during Dextrose Injection (5%) treatment.

10 OVERDOSAGE

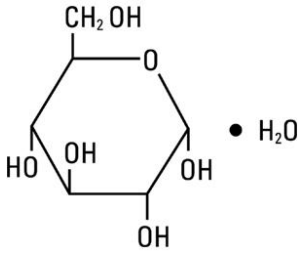
A medication error resulting in a high infusion rate of Dextrose Injection (5%) can cause hyperglycemia, hyperosmolality, and adverse effects on fluid and electrolyte balance *[see Warnings and Precautions (5.2, 5.6)]*.

Severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal. In the event of overdosage (overhydration or solute overload) during Dextrose Injection (5%) treatment, discontinue the infusion. Institute corrective measures such as administration of exogenous insulin, and treat adverse effects on the CNS, respiratory, and cardiovascular systems *[see Warnings and Precautions (5.2, 5.6)]*.

11 DESCRIPTION

Dextrose, 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, USP (5%) is a clear, sterile, non-pyrogenic solutions 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, 100 mL, and 250 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 supplied as single-dose containers. The pH is 4.3 (range is 3.2 to 6.5).

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

Strength	Fill Volume	Amount of Dextrose Hydrous per Container	kcal* per Container	mOsmol per Liter
5% Dextrose Injection, USP (50 mg/mL)	50 mL	2.5 grams	8.5	253
	100 mL	5 grams	17	253
	250 mL	12.5 grams	42.5	253

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

Dextrose is derived from corn.

Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.

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, USP (5%) is a clear, colorless, sterile solution of dextrose supplied in single-dose flexible plastic ADD-Vantage™ diluent containers. This dosage form is intended to be used as a diluent for the contents of an ADD-Vantage vial or a single-dose powdered drug vial with a 20 mm closure using the ADD-Vantage ADDAPTOR™.

Unit of Sale	Strength	Volume
NDC 0409-7100-66 Case of 50 – 50 mL bags	5% (2.5 g/50 mL) (50 mg/mL)	50 mL bags
NDC 0409-7100-67 Case of 50 – 100 mL bags	5% (5 g/100 mL) (50 mg/mL)	100 mL bags
NDC 0409-7100-02 Case of 24 – 250 mL bags	5% (12.5 g/250 mL) (50 mg/mL)	250 mL bags

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

Use the product immediately after the introduction of additives.

Storage and Handling

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

Do not freeze.

To contact Pfizer's Medical Information Department, please visit www.pfizermedinfo.com or call 1-800-438-1985.

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