

DEXTROSE- dextrose monohydrate injection, solution

REMEDYREPACK INC.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use DEXTROSE INJECTION (50%) safely and effectively. See full prescribing information for DEXTROSE INJECTION (50%).

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

RECENT MAJOR CHANGES

Dosage and Administration (2.2)	07/2025
Contraindications (4)	07/2025
Warnings and Precautions (5.1, 5.2, 5.3, 5.4, 5.5, 5.6)	07/2025

INDICATIONS AND USAGE

Dextrose Injection (50%) is indicated for the treatment of insulin-induced hypoglycemia (e.g., hyperinsulinemia, insulin shock) in adults and pediatric patients 2 years of age and older. (1)

DOSAGE AND ADMINISTRATION

- Only for intravenous infusion. Do not administer subcutaneous or intramuscularly. (2.1)
- Adults and Pediatric Patients 12 years of Age and Older
- Administer into a central vein or large peripheral vein.
- Recommended dosage is 10 to 25 grams (20 to 50 mL) administered once. Repeated doses may be administered as clinically appropriate. (2.2)
- Pediatric Patients 2 to 11 Years of Age
- Administer into a central vein
- Appropriate dosage depends on the age, weight, clinical and metabolic conditions of the patient, and concomitant therapy. (2.2)
- Maximum rate of dextrose administration without producing hyperglycemia is 0.5 g/kg of body weight/hour. (2.2)
- See full prescribing information for more information on preparation and administration instructions. (2.12.2)

DOSAGE FORMS AND STRENGTHS

Injection: 50% (25 g/50 mL) (500 mg/mL) of single-dose dextrose hydrous supplied as: (3)

-
- Ansyr[®] II Plastic Syringe with syringe and barrel detached

CONTRAINDICATIONS

- Intracranial or intraspinal hemorrhage. (4)
- Severe dehydration. (4)
- Alcohol withdrawal. (4)
- Known hypersensitivity to dextrose. (4)

WARNINGS AND PRECAUTIONS

- Hyperglycemia or Hyperosmolar Syndrome: Monitor blood and urine glucose; administer insulin as needed. (5.1)
- Hypersensitivity Reactions: Monitor for signs and symptoms and discontinue infusion immediately if reaction occurs. (5.2)
- Phlebitis and Thrombosis: Remove catheter as soon as possible if thrombophlebitis develops. (2.1, 5.3)
- Electrolyte Imbalance and Fluid Overload: Monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during administration. (5.4)
- Hyponatremia: Monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and neurologic status. (5.5)
- Potential Aluminum Toxicity for Patients with Immature or Impaired Renal Function: Prolonged

administration of Dextrose Injection (50%) may lead to toxic levels of aluminum in pediatric patients with immature renal function or renal impairment, and in adults with renal impairment. (5.6)

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. Use a different dextrose product if treatment is necessary in a pediatric patient younger than 2 years old. (8.4)

Revised: 9/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

2.1 Important Preparation and Administration Instructions

2.2 Recommended Dosage and Administration

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

5.1 Hyperglycemia and Hyperosmolar Hyperglycemic State

5.2 Hypersensitivity Reactions

5.3 Phlebitis and Thrombosis

5.4 Electrolyte Imbalance and Fluid Overload

5.5 Hyponatremia

5.6 Potential Aluminum Toxicity for Patients with Immature or Impaired Renal Function

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS

7.1 Drugs with Effects on Glycemic Control and Electrolyte Balance

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Lactation

8.4 Pediatric Use

8.5 Geriatric Use

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

16 HOW SUPPLIED/STORAGE AND HANDLING

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Dextrose (50%) Injection is indicated for the treatment of insulin-induced hypoglycemia (e.g., hyperinsulinemia, insulin shock) in adults and pediatric patients 2 years of age and older.

2 DOSAGE AND ADMINISTRATION

2.1 Important Preparation and Administration Instructions

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use Dextrose Injection (50%) if the solution is cloudy or the seal has been broken.
- Obtain a blood glucose level prior to administering Dextrose Injection (50%). However, in an emergency, administer Dextrose Injection (50%) promptly without awaiting blood glucose test results.
- Do not administer Dextrose Injection (50%) simultaneously with blood through the same infusion set because pseudoagglutination of red blood cells may occur.
- Administer Dextrose Injection (50%) intravenously. Do not administer Dextrose Injection (50%) subcutaneously or intramuscularly.
- Discard the unused portion.

2.2 Recommended Dosage and Administration

Adults and Pediatric Patients 12 Years of Age and Older

When possible, administer Dextrose Injection (50%) into a central vein or large peripheral vein because Dextrose Injection (50%) has an osmolarity greater than 900 mOsm/L and can cause venous irritation.

The recommended dosage of Dextrose Injection (50%) is 10 to 25 grams (20 to 50 mL) of Dextrose Injection (50%), administered once via intravenous infusion. Repeated doses may be administered as clinically appropriate.

Slowly infuse Dextrose Injection (50%) to reduce the risk of developing hyperglycemia and to minimize venous irritation [see *Warnings and Precautions (5.1, 5.3)*]. The maximum rate at which Dextrose Injection (50%) can be infused without producing hyperglycemia is 0.5 g/kg of body weight/hour.

Pediatric Patients 2 to 11 Years of Age

Administer Dextrose Injection (50%) into a central vein. Avoid administration of Dextrose Injection (50%) into a peripheral vein because Dextrose Injection (50%) has an

osmolarity greater than 900 mOsm/L and can cause venous irritation [*Warnings and Precautions (5.3)*] . If central venous access cannot be obtained, consider using an alternative commercially available dextrose product with a lower concentration.

The appropriate dosage of Dextrose Injection (50%) depends on the age, weight, clinical and metabolic conditions of the patient, and concomitant therapy.

Slowly infuse Dextrose Injection (50%) to reduce the risk of developing hyperglycemia and to minimize venous irritation [*see Warnings and Precautions (5.1, 5.3)*] . The maximum rate at which Dextrose Injection (50%) can be infused without producing hyperglycemia is 0.5 g/kg of body weight/hour.

3 DOSAGE FORMS AND STRENGTHS

Injection: 50% (25 g/50 mL) (500 mg/mL) of dextrose hydrous in a clear, colorless solution supplied as:

- Single-dose Ansyr[®] II Plastic Syringe with syringe and barrel detached

4 CONTRAINDICATIONS

Dextrose Injection (50%) is contraindicated in patients with:

- Intracranial or intraspinal hemorrhage because Dextrose Injection (50%) can worsen cerebral edema by causing a fluid shift across the blood-brain barrier.
- Severe dehydration because of the potential to worsen the patient's hyperosmolar state.
- Alcohol withdrawal because of the potential to precipitate Wernicke encephalopathy (WE) or cardiomyopathy in thiamine-deficient patients.
- Known hypersensitivity to dextrose [*see Warnings and Precautions (5.2)*] .

5 WARNINGS AND PRECAUTIONS

5.1 Hyperglycemia and Hyperosmolar Hyperglycemic State

Significant hyperglycemia and hyperosmolar hyperglycemic state may result from too rapid administration of Dextrose Injection (50%). Symptoms of hyperosmolar hyperglycemic state include mental confusion and loss of consciousness. To minimize these risks, slowly infuse Dextrose Injection (50%) and monitor blood and urine glucose during treatment with Dextrose Injection (50%).

If Dextrose Injection (50%) is abruptly discontinued, patients should receive 5% or 10% dextrose injection to avoid rebound hypoglycemia.

5.2 Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, have been reported with Dextrose Injection (50%) administration [*see Adverse Reactions (6)*] . Stop administration of Dextrose Injection (50%) immediately if signs or symptoms of a hypersensitivity reaction develop. Initiate appropriate treatment as clinically indicated.

5.3 Phlebitis and Thrombosis

Dextrose Injection (50%) is hypertonic (has an osmolarity greater than 900 mOsm/L) and may cause phlebitis and thrombosis at the site of injection. If thrombophlebitis occurs, remove the catheter as soon as possible.

Administer Dextrose Injection (50%) via slow intravenous infusion into a central vein (when possible) to reduce the risk of phlebitis and thrombosis. Ensure that the needle is well within the lumen of the vein and that extravasation does not occur. If thrombosis occurs, stop administration of Dextrose Injection (50%) and initiate corrective measures. Avoid administration of Dextrose Injection (50%) into a peripheral vein in pediatric patients 2 to 11 years old. If central venous access cannot be obtained in these pediatric patients, consider using an alternative commercially available dextrose product with a lower concentration.

Do not administer Dextrose Injection (50%) subcutaneously or intramuscularly.

5.4 Electrolyte Imbalance and Fluid Overload

Electrolyte deficits, particularly serum potassium and phosphate, may occur during prolonged use of Dextrose Injection (50%).

Depending on the administered volume and the infusion rate, administration of Dextrose Injection (50%) can cause fluid overload including pulmonary edema.

Avoid Dextrose Injection (50%) 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.

5.5 Hyponatremia

Dextrose Injection (50%) 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 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) and Use in Specific Populations (8.4)*] .

Avoid Dextrose Injection (50%) 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 (5.4)*] .

5.6 Potential Aluminum Toxicity for Patients with Immature or Impaired Renal Function

Dextrose Injection (50%) contains up to 600 mcg/L of aluminum. Prolonged administration of Dextrose Injection (50%) may lead to toxic levels of aluminum in pediatric patients with immature renal function. Due to the potential for excessive aluminum exposure, Dextrose Injection (50%) is not approved for pediatric patients younger than 2 years of age. Parenteral aluminum exposure greater than 4 to 5 mcg/kg/day has been associated with central nervous system and bone toxicity in this

age group.

Prolonged administration of Dextrose Injection (50%) may also lead to toxic levels of aluminum in adults and pediatric patients with renal impairment.

6 ADVERSE REACTIONS

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

- Hyperglycemia and Hyperosmolar Syndrome *[see Warnings and Precautions (5.1)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.2)]*
- Phlebitis and Thrombosis *[see Warnings and Precautions (5.3)]*
- Electrolyte Imbalance and Fluid Overload *[see Warnings and Precautions (5.4)]*
- Hyponatremia *[see Warnings and Precautions (5.5)]*

The following adverse reactions associated with the use of Dextrose Injection 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 always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

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

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

Cardiovascular disorders: cyanosis, volume overload

7 DRUG INTERACTIONS

7.1 Drugs with Effects on Glycemic Control and Electrolyte Balance

Dextrose Injection (50%) can affect glycemic control, vasopressin, and fluid and/or electrolyte balance *[see Warnings and Precautions (5.1, 5.4, 5.5)]*. Monitor patients' blood glucose concentrations, fluid balance, serum electrolyte concentrations, and acid-base balance.

Concomitant administration of Dextrose Injection (50%) 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 (50%) 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

Appropriate administration of Dextrose Injection (50%) 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. Animal reproduction studies have not been conducted with dextrose.

The background risk of major birth defects and miscarriage in patients with insulin-induced hypoglycemia (e.g., hyperinsulinemia, insulin shock) 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 effects of Dextrose Injection (50%) 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 (50%) and any potential adverse effects on the breastfed infant from Dextrose Injection (50%) or from the underlying maternal condition.

8.4 Pediatric Use

Dextrose Injection (50%) is indicated in pediatric patients aged 2 years and older for the treatment of insulin-induced hypoglycemia (e.g., hyperinsulinemia, or insulin shock).

Monitor plasma electrolyte concentrations closely in pediatric patients who may have impaired ability to regulate fluids and electrolytes [see *Warnings and Precautions* (5.4)] . Pediatric patients treated with Dextrose Injection (50%) are at increased risk of developing hyponatremia and hyponatremic encephalopathy [see *Warnings and Precautions* (5.5)] .

Dextrose Injection (50%) is not indicated for use in neonates. Dextrose Injection (50%) can increase the risk of developing hypo- or hyperglycemia in neonates, especially preterm neonates with low birth weight. Excessive or rapid administration of Dextrose Injection (50%) may also result in increased serum osmolality and risk of intracerebral hemorrhage in very low birth weight neonates.

Dextrose Injection (50%) is not indicated for use in pediatric patients younger than 2 years old due to the potential for excessive aluminum exposure. If treatment with Dextrose Injection (50%) is necessary in a pediatric patient younger than 2 years old, use a different dextrose product [see *Indications and Usage* (1) and *Warnings and Precautions* (5.6)] .

8.5 Geriatric Use

Dextrose Injection (50%) has not been studied in a sufficient number of patients aged 65 and over to determine whether they respond differently from younger adult 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

low and be titrated up cautiously, reflecting the 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 (50%) 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 (50%) treatment.

10 OVERDOSAGE

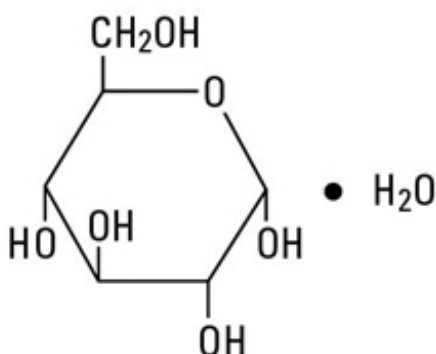
A medication error resulting in a high infusion rate of Dextrose Injection (50%) can cause hyperglycemia, hyperosmolality, and adverse effects on fluid and electrolyte balance [see *Warnings and Precautions* (5.1, 5.4)] .

Severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal. In the event of overdosage (overhydration or solute overload) during Dextrose Injection (50%) 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* (5.1, 5.4)] .

11 DESCRIPTION

Dextrose, USP is chemically designated $C_6H_{12}O_6 \cdot H_2O$ (D-glucose monohydrate), a hexose sugar freely soluble in water.

Dextrose, hydrous has the following structural formula:



Water for Injection, USP is chemically designated H_2O . The molecular weight of dextrose (D-glucose) monohydrate is 198.17.

Dextrose Injection, USP (50%) is a sterile, nonpyrogenic, hypertonic solution of dextrose in water for injection for intravenous injection.

Each milliliter (mL) of fluid contains 0.5 grams of dextrose, hydrous which delivers 3.4 kcal/gram (0.85 kcal/mL). The solution has an osmolarity of 2.53 mOsmol/mL (calculation) and the pH range is 3.2 to 6.5. May contain sodium hydroxide and/or hydrochloric acid for pH adjustment.

The Dextrose Injection (50%) vial contains no more than 600 mcg/L of aluminum.

The solution contains no bacteriostatic, antimicrobial agent or added buffer (except for pH adjustment) and is supplied as single-dose containers.

Dextrose is derived from corn.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Dextrose restores blood glucose levels and provides a source of carbohydrate calories.

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 (50%) is supplied as a clear, colorless solution in single-dose containers as follows:

50 mL Ansyr® II Plastic Syringe with syringe and barrel detached 50% (25 g/50 mL) (0.5 g/mL)

NDC: 70518-4219-00

NDC: 70518-4219-01

PACKAGING: 10 in 1 CONTAINER

PACKAGING: 1 in 1 CARTON, 50 mL in 1 SYRINGE PLASTIC TYPE 2

Storage and Handling

Minimize exposure of Dextrose Injection (50%) to heat. Avoid excessive heat. Protect from freezing. Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature.]

Repackaged and Distributed By:

Remedy Repack, Inc.

PRINCIPAL DISPLAY PANEL

- WATER
- SODIUM HYDROXIDE
- HYDROCHLORIC ACID

remedy
repack

RX ONLY

Repackaged By:
RemedyRepack Inc.,
Indiana, PA 15701, 724.465.8762

[illegible]

Dextrose 50% Injection

Ansyr II

NDC #: 70518-4219-01

Expires:

For intravenous use.; Discard
unused portion.; Prefilled

LOT #:

Org NDC: 00409-7517-16

MFG: Hospira, Inc, Lake Forest, IL
60045

Unit of Use Syringe.

25g / 50mL (0.5g/mL)

QTY: 1 50mL Syringe

WARNING: Medication and fluid path are
sterile and nonpyrogenic if cap is in place
and package is intact.

Usual Dosage: See Insert

Keep this and all medication out
of the reach of children
Store at 20-25°C (68-77°F);
excursions permitted to 15-30°C
(59-86°F) [See USP]



RX ONLY

Repackaged By:
RemedyRepack Inc.,
Indiana, PA 15701, 724.465.8762

10/23/2024
10/23/2024
10/23/2024
10/23/2024
10/23/2024
10/23/2024
10/23/2024
10/23/2024
10/23/2024
10/23/2024

DEXTROSE

dextrose monohydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70518-4219(NDC:0409- 7517)
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SLOG7R0OK)	DEXTROSE MONOHYDRATE	25 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70518- 4219-0	10 in 1 CONTAINER	10/23/2024	
1		1 in 1 CARTON		
1	NDC:70518- 4219-1	50 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019445	10/23/2024	

Labeler - REMEDYREPACK INC. (829572556)

Revised: 9/2025

REMEDYREPACK INC.