DEXTROSE- dextrose injection, solution
Henry Schein, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

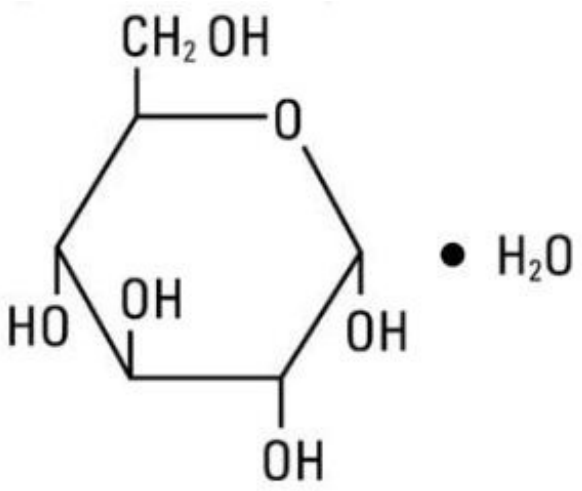
50% Dextrose Injection, USP 25 grams (0.5g/ml)

NOTE: This solution is hypertonic - See WARNINGS and PRECAUTIONS.
LifeShield® Abboject® Syringe Fliptop Container

Ansyr™ II Plastic Syringe
Rx only

Description

50% Dextrose Injection, USP is a sterile, nonpyrogenic, hypertonic solution of dextrose in water for injection for intravenous injection
as a fluid and nutrient replenisher.
Each mL of fluid contains 0.5 g dextrose, hydrous which delivers 3.4 kcal/gram. The solution has an osmolarity of 2.53 mOsmol/mL
(calc.), a pH of 4.2 (3.2 to 6.5) and may contain sodium hydroxide and/or hydrochloric acid for pH adjustment.
The solution contains no bacteriostat, antimicrobial agent or added buffer (except for pH adjustment) and is intended only for use as a
single-dose injection. When smaller doses are required, the unused portion should be discarded with the entire unit.
Dextrose, USP is chemically designated C6H12O6• H2O (D-glucose monohydrate), a hexose sugar freely soluble in water. Dextrose,
hydrous has the following structural formula:



Water for Injection, USP is chemically designated H2O .
The syringe is molded from a specially formulated polypropylene. Water permeates from inside the container at an extremely slow

rate which will have an insignificant effect on solution concentration over the expected shelf life. Solutions in contact with the
plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was
supportive of the safety of the syringe material.

CLINICAL PHARMACOLOGY

When administered intravenously this solution restores blood glucose levels in hypoglycemia and provides a source of carbohydrate
calories.
Carbohydrate in the form of dextrose may aid in minimizing liver glycogen depletion and exerts a protein-sparing action. Dextrose
injection undergoes oxidation to carbon dioxide and water.
Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult
requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).
Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of
electrolytes in the body compartments and sodium (Na+) plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE

50% Dextrose Injection is indicated in the treatment of insulin hypoglycemia (hyperinsulinemia or insulin shock) to restore blood
glucose levels.
The solution is also indicated, after dilution, for intravenous infusion as a source of carbohydrate calories in patients whose oral intake
is restricted or inadequate to maintain nutritional requirements. Slow infusion of hypertonic solutions is essential to insure proper
utilization of dextrose and avoid production of hyperglycemia.

CONTRAINDICATIONS

A concentrated dextrose solution should not be used when intracranial or intraspinal hemorrhage is present, nor in the presence of
delirium tremens if the patient is already dehydrated.
Dextrose injection without electrolytes should not be administered simultaneously with blood through the same infusion set because of
the possibility that pseudoagglutination of red cells may occur.

WARNINGS

50% Dextrose Injection is hypertonic and may cause phlebitis and thrombosis at the site of injection.
Significant hyperglycemia and possible hyperosmolar syndrome may result from too

rapid administration. The physician should be
aware of the symptoms of hyperosmolar syndrome, such as mental confusion and loss of consciousness, especially in patients with
chronic uremia and those with known carbohydrate intolerance.
The intravenous administration of this solution can cause fluid and/or solute overloading resulting in dilution of serum electrolyte
concentrations, overhydration, congested states or pulmonary edema.
Additives may be incompatible. Consult with pharmacist if available. When introducing additives, use aseptic technique, mix
thoroughly and do not store.
For peripheral vein administration:
The solution should be given slowly, preferably through a small bore needle into a large vein, to minimize venous irritation.
For central venous administration:
Concentrated dextrose should be administered via central vein only after suitable dilution.

PRECAUTIONS

Do not use unless the solution is clear and seal is intact. Discard unused portion.

Electrolyte deficits, particularly in serum potassium and phosphate, may occur during prolonged use of concentrated dextrose solutions. Blood electrolyte monitoring is essential and fluid and electrolyte imbalances should be corrected. Essential vitamins and minerals also should be provided as needed.

To minimize hyperglycemia and consequent glycosuria, it is desirable to monitor blood and urine glucose and if necessary, add insulin.

When a concentrated dextrose infusion is abruptly withdrawn, it is advisable to follow with the administration of 5% or 10% dextrose injection to avoid rebound hypoglycemia.

Solutions containing dextrose should be used with caution in patients with known subclinical or overt diabetes mellitus.

Care should be exercised to insure that the needle is well within the lumen of the vein and that extravasation does not occur. If thrombosis should occur during administration, the injection should be stopped and corrective measures instituted.

Concentrated dextrose solutions should not be administered subcutaneously or intramuscularly.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Studies with solutions in polypropylene syringes have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy
Animal reproduction studies have not been conducted with dextrose. It is also not known whether dextrose can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose should be given to a pregnant woman only if clearly needed.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are

excreted in human milk, caution should be exercised when 50% Dextrose Injection, USP is administered to a nursing mother.

ADVERSE REACTIONS

Hyperosmolar syndrome, resulting from excessively rapid administration of concentrated dextrose may cause mental confusion and/or loss of consciousness.

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.
If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of overhydration or solute overload during therapy, re-evaluate the patient and institute appropriate corrective measures.
See WARNINGS and PRECAUTIONS.

DOSAGE AND ADMINISTRATION

For peripheral vein administration:
Injection of the solution should be made slowly.
The maximum rate at which dextrose can be infused without producing glycosuria is 0.5 g/kg of body weight/hour. About 95% of the dextrose is retained when infused ata rate of 0.8 g/kg/hr.
In insulin-induced hypoglycemia, intravenous injection of 10 to 25 grams of dextrose (20 to 50 mL of 50% dextrose) is usually adequate. Repeated doses and supportive treatment may be required in severe cases. A specimen for blood glucose determination should be taken before injecting the dextrose. In such emergencies, dextrose should be administered promptly without awaiting pretreatment test results.
For central venous administration:
For total parenteral nutrition 50% Dextrose Injection, USP is administered by slow intravenous infusion (a) after admixture with amino acid solutions via an indwelling catheter with the tip positioned in a large central vein, preferably the superior vena cava, or (b) after dilution with sterile water for injection. Dosage should be adjusted to meet individual patient requirements.
Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.
The maximum rate of dextrose administration which does not result in glycosuria is the

same as cited above.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever
solution and container permit. See CONTRAINDICATIONS.

HOW SUPPLIED

50% Dextrose Injection, USP is supplied in single-dose containers as follows:

Unit of Sale	Concentration
NDC 0409-4902-34	25 g/50 mL
Bundle containing 10 LifeShield® Abboject® Unit of Use Syringe with male luer	(0.5 g/mL)
lock adapter and protected needle	
NDC 0409-6648-02	25 g/50 mL
Tray containing 25 50 mL Single-Dose Fliptop Vials	(0.5 g/mL)
NDC 0409-7517-16	25 g/50 mL
Bundle containing 10 Ansyr™ II Plastic Syringe with syringe and barrel detached	(0.5 g/mL)

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Product repackaged by: Henry Schein, Inc., Bastian, VA 24314

From Original Manufacturer/Distributor's NDC and Unit of Sale	To Henry Schein Repackaged Product NDC and Unit of Sale	Total Strength/Total Volume (Concentration) per unit
NDC 0409-4902-34 Bundle containing 10 Lifeshield® Abboject® Unit of Use Syringe	NDC 0404-9846-50 1 LIfeshield® Abboject® Unit of Use Syringe per bag (Syringe bears NDC 0409-4902-64)	25 g/50 mL (0.5 g/mL)
NDC 0409-6648-02 Tray containing 25 50 mL Single-Dose Fliptop Vials	NDC 0404-9847-50 1 Single-Dose Fliptop Vial per bag (Vial bears NDC 0409-6648-16)	25 g/50 mL (0.5 g/mL)

NDC 0409-7517-16 Bundle containing 10 Ansyr™ II Plastic Syringe	NDC 0404-9845-50 1 Ansyr™ II Plastic Syringe per bag (Syringe bears NDC 0409-7517-66)	25 g/50 mL (0.5mg/mL)

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Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

LAB-1027-3.0

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Sample Package Label

DEXTROSE

dextrose injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0404-9846(NDC:0409-4902)
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	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:0404-9846-50	1 in 1 BAG	01/10/2022	
1		1 in 1 CARTON		
1		50 mL in 1 SYRINGE, GLASS; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/10/2022	

Labeler - Henry Schein, Inc. (012430880)

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