DEXTROSE- dextrose monohydrate injection, solution
Hospira, Inc.

50% and 70% Dextrose Injection, USP

Concentrated Dextrose in Water

Pharmacy Bulk Package — Not For Direct Infusion.
FOR USE ONLY WITH AUTOMATED COMPOUNDING DEVICES.

NOTE: These solutions are hypertonic – see *WARNINGS* and *PRECAUTIONS*.

Flexible Plastic Containers

Rx only

DESCRIPTION

50% and 70% Dextrose Injection, USP (concentrated dextrose in water) are sterile, nonpyrogenic, hypertonic solutions of Dextrose, USP in water for injection for intravenous administration after appropriate admixture or dilution.

The Pharmacy Bulk Package is a sterile dosage form which contains multiple single doses for use only in a pharmacy bulk admixture program.

The content and physical characteristics of the solutions are as follows:

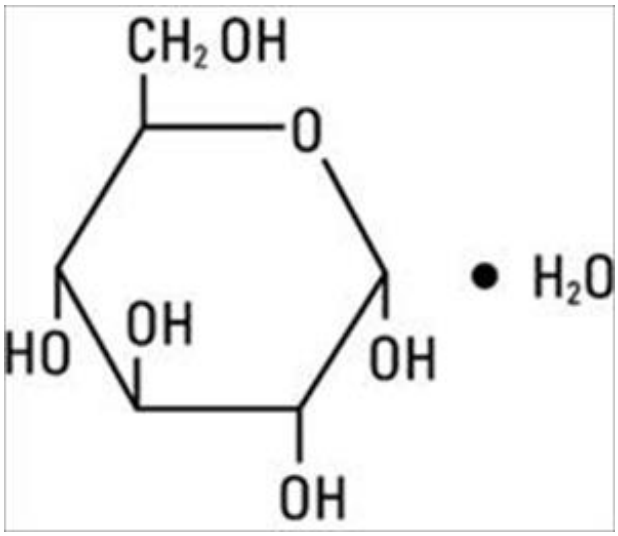
Solution Characteristics	50% Dextrose Injection, USP	70% Dextrose Injection, USP
pH	4.0	4.0
pH range	3.2 - 6.5	3.2 - 6.5
Osmolarity (mOsmol/L) (calc.)	2523	3532
Specific Gravity	1.170	1.236
Grams Dextrose/100 mL	50	70
kcal/100 mL*	170	238
Fill volume (mL)	2000	2000
* Caloric value calculated on the basis of 3.4 kcal/g of dextrose, hydrous.		

The solutions contain no bacteriostat, antimicrobial agent or added buffer and are intended only for use as a single-dose injection following admixture or dilution.

This Pharmacy Bulk Package is intended only for use in the preparation of sterile, intravenous nutrient admixtures using automated compounding devices. The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly. 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 plastic container materials. 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.

Dextrose Injection, USP is a parenteral fluid and nutrient replenisher.

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



Water for Injection, USP is chemically designated H_2O.

CLINICAL PHARMACOLOGY

When administered intravenously, solutions containing carbohydrate in the form of dextrose restore blood glucose levels and provide 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 daily 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% and 70% Dextrose Injection, USP (concentrated dextrose in water) in Pharmacy Bulk Packages are indicated for use with automated compounding devices for preparing intravenous nutritional admixtures in the pharmacy.

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

Concentrated dextrose in water should be administered only after suitable dilution. Hypertonic dextrose solutions should be given slowly. 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 these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

FOR PERIPHERAL VEIN ADMINISTRATION

Hypertonic dextrose solutions (above 5% concentration) 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 after appropriate admixture or dilution when required.

PRECAUTIONS

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

Aseptic technique is essential with the use of sterile preparations for compounding nutritional admixtures. Discard container within 4 hours of entering closure.

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 (or catheter) is well within the lumen of the vein and that extravasation does not occur.

Concentrated dextrose solutions should not be administered subcutaneously or intramuscularly.

Do not administer unless solution is clear and container is undamaged.

Pregnancy Category C: 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.

Pediatric Use

The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance. Caution should be exercised with low birth weight premature neonates, who are receiving dextrose concentrations of 10% or greater, as they are most susceptible to glucose intolerance and hyperglycemia. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage.

ADVERSE REACTIONS

Hyperosmolar syndrome, resulting from excessively rapid administration of concentrated dextrose may cause hypovolemia, dehydration, 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

Concentrated Dextrose in Water is administered by slow intravenous infusion (a) after admixture with amino acid solutions or (b) after dilution with other compatible IV fluids. Dosage should be adjusted to meet the requirements of each individual patient.

50% and 70% Dextrose Injection, USP in the 2000 mL flexible Pharmacy Bulk Package are designed for use with automated compounding devices for preparing intravenous nutritional admixtures. Dosages will be in accordance with the recommendation of the prescribing physician. 50% and 70% Dextrose Injection, USP are not intended for direct infusion. Admixtures should be made by, or under the direction of, a pharmacist using strict aseptic technique under a laminar flow hood. Compounded admixtures may be stored under refrigeration for up to 24 hours. Administration of admixtures should be completed within 24 hours after removal from refrigeration.

The maximum rate at which dextrose can be infused without producing glycosuria is 0.5 g/kg of body weight/hr. About 95% of the dextrose is retained when infused at a rate of 0.8 g/kg/hr.

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.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. (See ***PRECAUTIONS***.)

Drug Interactions

Additives may be incompatible with the fluid withdrawn from this container. Consult with pharmacist, if available. When compounding admixtures, use aseptic technique, mix thoroughly and do not store.

Some opacity of the plastic due to moisture absorption during sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually.

Recommended Directions for Use of the Pharmacy Bulk Package Use Aseptic Technique

1. During use, container must be stored, and all manipulations performed, in an appropriate laminar flow hood.

2. Remove cover from outlet port at bottom of container.
3. Insert piercing pin of transfer set and suspend unit in a laminar flow hood. Insertion of a piercing pin into the outlet port should be performed only once in a Pharmacy Bulk Package solution. Once the outlet site has been entered, the withdrawal of container contents should be completed promptly in one continuous operation. Should this not be possible, a maximum time of 4 hours from transfer set pin or implement insertion is permitted to complete fluid transfer operations; i.e., discard container no later than 4 hours after initial closure puncture.
4. Sequentially dispense aliquots of 50% or 70% Dextrose Injection, USP into IV containers using appropriate transfer set. During fluid transfer operations, the Pharmacy Bulk Package should be maintained under the storage conditions recommended in the labeling.

HOW SUPPLIED

50% and 70% Dextrose Injection, USP are supplied as follows:

NDC No.	Container	Concentration	Fill
0409-7119-07	Flexible Pharmacy Bulk Package	50%	2000 mL
0409-7120-07	Flexible Pharmacy Bulk Package	70%	2000 mL

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing.

Revised: June, 2010

Printed in USA EN-2527

Hospira, Inc., Lake Forest, IL 60045 USA

IM-1347

2000 mL

NDC 0409-7119-07

50% DEXTROSE INJECTION, USP

1750

1500

1250

1000

750

500

250

Pharmacy Bulk Package —
Not For Direct Infusion.
MUST BE DILUTED.

EACH 100 mL CONTAINS DEXTROSE, HYDROUS, USP 50 g IN WATER FOR INJECTION.
HYPERTONIC OSMOLARITY 2523 mOsmol/LITER (calc).
pH 4.0 (3.2 to 6.5) SPECIFIC GRAVITY 1.170
STERILE, NONPYROGENIC.

DOSAGE AND ADMINISTRATION: SEE PACKAGE INSERT.

CAUTION: DO NOT USE UNLESS SOLUTION IS CLEAR, CLOSURE IS INTACT, AND CONTAINER IS UNDAMAGED. CHECK FOR MINUTE LEAKS BY SQUEEZING FIRMLY. IF LEAKS ARE FOUND DISCARD CONTAINER AND CONTENTS AS STERILITY MAY BE IMPAIRED. **WITHIN 4 HOURS AFTER INITIAL ENTRY DISCARD CONTAINER AND UNUSED CONTENTS.**

(01)00304097119073

DATE ENTERED: _____

TIME OF ENTRY: _____

STORE AT 20 TO 25°C (68 TO 77°F). [SEE USP CONTROLLED ROOM TEMPERATURE.] PROTECT FROM FREEZING.

THIS PRODUCT CONTAINS NO MORE THAN 25 mcg/L OF ALUMINUM.

Rx ONLY

50%

3 V
CONTAINS DEHP

LATEX

IM-1347 (10/06)

PRINTED IN USA
HOSPIRA, INC., LAKE FOREST, IL 60045 USA

Hospira

IM-1398

2000 mL

NDC 0409-7120-07

DEXTROSE INJECTION, USP 70%

Pharmacy Bulk Package —
Not For Direct Infusion.
MUST BE DILUTED.

EACH 100 mL CONTAINS DEXTROSE, HYDROUS, USP 70 g IN WATER FOR INJECTION.
HYPERTONIC OSMOLARITY 3532 mOsmol/LITER (calc).
pH 4.0 (3.2 to 6.5) SPECIFIC GRAVITY 1.236
STERILE, NONPYROGENIC.
DOSAGE AND ADMINISTRATION: SEE PACKAGE INSERT.
CAUTION: DO NOT USE UNLESS SOLUTION IS CLEAR, CLOSURE IS INTACT, AND CONTAINER IS UNDAMAGED. CHECK FOR MINUTE LEAKS BY SQUEEZING FIRMLY. IF LEAKS ARE FOUND DISCARD CONTAINER AND CONTENTS AS STERILITY MAY BE IMPAIRED. **WITHIN 4 HOURS AFTER INITIAL ENTRY DISCARD CONTAINER AND UNUSED CONTENTS.**
DATE ENTERED:_____
TIME OF ENTRY: _____
STORE AT 20 TO 25°C (68 TO 77°F). [SEE USP CONTROLLED ROOM TEMPERATURE.] PROTECT FROM FREEZING.
THIS PRODUCT CONTAINS NO MORE THAN 25 mcg/L OF ALUMINUM.
Rx ONLY

(01)00304097120079

1750
1500
1250
1000
750
500
250

70%

3 V CONTAINS DEHP

LATEX

IM-1398 (11/06)

PRINTED IN USA
HOSPIRA, INC., LAKE FOREST, IL 60045 USA

Hospira

DEXTROSE

dextrose monohydrate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0409-7120
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (ANHYDROUS DEXTROSE)	DEXTROSE MONOHYDRATE	70 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0409-7120-07	6 in 1 CASE		
1		1 in 1 POUCH		
1		2000 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019893	12/26/1989	

DEXTROSE

dextrose monohydrate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0409-7119
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (ANHYDROUS DEXTROSE)	DEXTROSE MONOHYDRATE	50 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0409-7119-07	6 in 1 CASE		
1		1 in 1 POUCH		

1		2000 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019894	12/26/1989	10/01/2011

Labeler - Hospira, Inc. (141588017)

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