DEXTROSE- dextrose injection, solution
B. Braun Medical Inc.

5% Dextrose Injection USP

Partial Fill

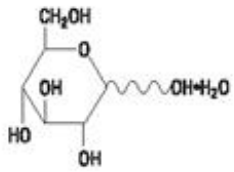
DESCRIPTION

Each mL of 5% Dextrose Injection USP contains:
Hydrous Dextrose USP 50 mg; Water for Injection USP qs

pH: 4.5 (3.5–6.5)
Calculated Osmolarity: 250 mOsmol/liter
Calories per 100 mL: 17

This solution is sterile, nonpyrogenic, isotonic and contains no bacteriostatic or antimicrobial agents. This product is intended for intravenous administration.

The formula of the active ingredient is:

Ingredient	Molecular Formula	Molecular Weight
Hydrous Dextrose USP		198.17

Not made with natural rubber latex, DEHP, or PVC.

The plastic container is a copolymer of ethylene and propylene formulated and developed for parenteral drugs. The copolymer contains no plasticizers and exhibits virtually no leachability. The safety of the plastic container has been confirmed by biological evaluation procedures. The material passes Class VI testing as specified in the U.S. Pharmacopeia for Biological Tests — Plastic Containers. These tests have shown that the container is nontoxic and biologically inert.

The container/solution unit is a closed system and is not dependent upon entry of external air during administration. The container has two ports, one is for the intravenous administration set and the other is a medication addition site. Each is covered by a tamperproof barrier. Refer to the **Directions for Use** of the container to properly identify the ports.

No vapor barrier is necessary.

CLINICAL PHARMACOLOGY

5% Dextrose Injection USP provides calories and is a source of water for hydration. It is capable of inducing diuresis depending on the volume administered and the clinical condition of the patient.

Dextrose is readily metabolized, may decrease losses of body protein and nitrogen, promotes glycogen deposition and decreases or prevents ketosis if sufficient doses are provided.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirements range from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

INDICATIONS AND USAGE

5% Dextrose Injection USP is indicated for use in adults and pediatric patients as sources of calories and water for hydration.

This product is designed for use as a diluent and delivery system for intermittent intravenous administration of compatible drug additives. Consult prescribing information for **INDICATIONS AND USAGE** of drug additives to be administered in this manner.

CONTRAINDICATIONS

Solutions containing dextrose may be contraindicated in patients with hypersensitivity to corn products.

Do not administer 5% Dextrose Injection USP simultaneously with blood through the same infusion set because hemolysis or pseudoaggultination may occur.

WARNINGS

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of administered parenteral solutions.

Prolonged infusion of isotonic or hypotonic dextrose in water may increase the volume of extracellular fluid and cause water intoxication.

Solutions containing dextrose without electrolytes should not be administered simultaneously with blood through the same infusion set because of the possibility of agglomeration.

Excessive administration of potassium-free dextrose solutions may result in significant hypokalemia. Serum potassium levels should be maintained and potassium supplemented as required.

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

PRECAUTIONS

General

This solution should be used with care in patients with hypervolemia, renal insufficiency, urinary tract obstruction, or impending or frank cardiac decompensation.

Solutions containing dextrose should be used with caution in patients with overt or known subclinical diabetes mellitus or carbohydrate intolerance for any reason.

To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.

Laboratory Tests

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. Significant deviations from normal

concentrations may require tailoring of the electrolyte pattern, in this or an alternative solution(s).

Drug Interactions

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with 5% Dextrose Injection USP have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy -

Teratogenic Effects -

Pregnancy Category C.

Animal reproduction studies have not been conducted with 5% Dextrose Injection USP. It is also not known whether 5% Dextrose Injection USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 5% Dextrose Injection USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

As reported in the literature, dextrose solutions have been administered during labor and delivery. Caution should be exercised, and the fluid balance, glucose and electrolyte concentrations and acid-base balance, of both mother and fetus should be evaluated periodically or whenever warranted by the condition of the patient or fetus.

Nursing Mothers

Because many drugs are excreted in human milk, caution should be exercised when 5% Dextrose Injection USP is administered to a nursing woman.

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 in very small infants even small volumes of fluid may affect fluid and electrolyte balance. Care must be exercised in treatment of neonates, especially pre-term neonates, whose renal function may be immature and whose ability to excrete fluid and solute loads may be limited. Fluid intake, urine output, and serum electrolytes should be monitored closely.

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

Serum glucose concentrations should be frequently monitored when dextrose is prescribed to pediatric patients, particularly infants, neonates, and low birth weight infants. See **WARNINGS** and **DOSAGE AND ADMINISTRATION**.

Geriatric Use

An evaluation of current literature revealed no clinical experience identifying 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.

ADVERSE REACTIONS

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.

The physician should also be alert to the possibility of adverse reactions to drug additives diluted and administered from the plastic partial fill container. Prescribing information for drug additives to be administered in this manner should be consulted.

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 a fluid or solute overload, reevaluate the patient's condition, and institute appropriate corrective treatment.

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of administered parenteral solutions.

Prolonged infusion of isotonic or hypotonic dextrose in water may increase the volume of extracellular fluid and cause water intoxication.

DOSAGE AND ADMINISTRATION

This solution is for intravenous use only.

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations.

Do not use plastic container in series connection.

If administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

This solution is intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Use only if solution is clear and container and seals are intact.

When using this product as a diluent or vehicle for administration of drug additives, consult the prescribing information of the drug to be used.

Addition of medication should be accomplished using aseptic technique in order to assure sterility.

Physicochemical studies have shown that the container and solution can withstand freezing.

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

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

Pediatric Use

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.

There is no specific pediatric dose. The dose is dependent on weight, clinical condition, and laboratory results. Follow recommendations of appropriate pediatric reference text. See **WARNINGS** and **PRECAUTIONS**.

HOW SUPPLIED

5% Dextrose Injection USP is supplied sterile and nonpyrogenic in partial fill polyolefin containers. The 100/150 mL product is packaged 64 per case. The 50/100 mL product is packaged 84 per case. The 25/100 mL product is packaged 116 per case.

NDC	REF	Fill/Container (mL)
5% Dextrose Injection USP		
0264-1510-36	S5104-5410	25/100
0264-1510-31	S5104-5384	50/100
0264-1510-32	S5104-5264	100/150

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40°C does not adversely affect the product.

Rx only

Revised: May 2013

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Directions for Use of PAB® Container
Partial Additive Bag

Aseptic technique is required.

Caution: Before use, perform the following checks: Read the label. Ensure solution is the one ordered and is within the expiration date.

Inspect the solution in good light for cloudiness, haze or particulate matter; check the container for leakage or damage. Any container which is suspect should not be used.

Use only if solution is clear and container and seals are intact. Single dose container. Discard unused portion. Consult Package Insert for complete product information.

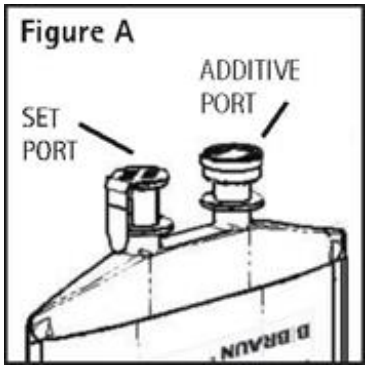
The physician should also be alert to the possibility of adverse reactions to drug additives diluted and administered from the plastic partial fill container. Prescribing information for drug additives to be administered in this manner should be consulted.

Do not use plastic container in series connection.

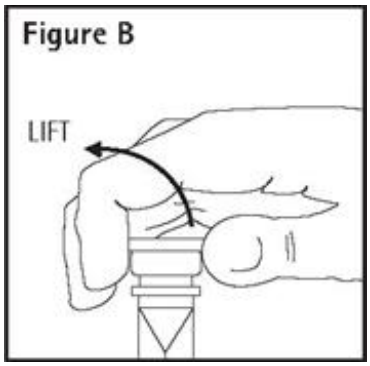
This solution is intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Physicochemical studies have shown that the container and solution can withstand freezing.

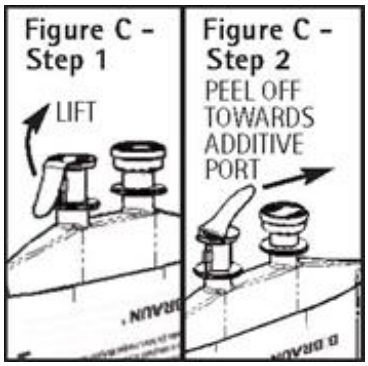
1. **Identify Two Ports (See Figure A).**



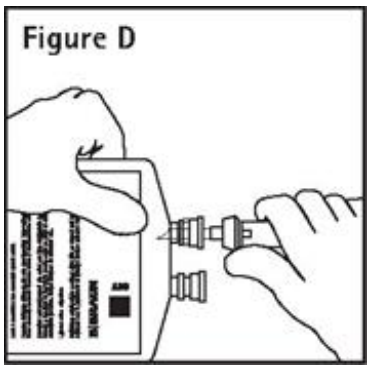
2. **To Add Medication**
   Remove additive port closure: hold container below additive port and grasp cap between thumb and forefinger then flip cap upward **(See Figure B). Swab exposed additive port.** Using a syringe with 18 gauge or smaller needle, insert cannula through resealable additive port and add desired drug. Mix thoroughly.
   Note: Partial fill bags have been designed to accept an overfill of up to 50 mL.



3. **To Attach Administration Set**
   To aseptically remove the set port closure: hold container below the set port and grasp the foil tab between the thumb and forefinger then pull the tab in two steps as shown in **Figure C Steps 1 and 2**.



4. Push spike through the diaphragm of the port **(See Figure D)**. Hang container using hole on the lower flap. Prime set in accordance with the **Directions for Use** provided with the set in use.



When the container is to be used as a diluent and delivery system for intermittent intravenous administration of compatible drug additives, consult prescribing information for **INDICATIONS AND USAGE** of drug additives to be administered in this manner.

Warning: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

PAB® containers can be safely transported in a standard 6-inch carrier through a pneumatic tube system that is well maintained and running properly.

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Irvine, CA 92614-5895 USA
1-800-227-2862
www.bbraun.com
Made in USA

Y36-002-839 LD-213-4

PRINCIPAL DISPLAY PANEL - 100 mL Partial Fill

NDC 0264-1510-32
S5104-5264

100 mL Partial Fill
in 150 mL
PAB® Container

5% Dextrose Injection USP

Each mL contains:
Hydrous Dextrose USP 50 mg
Water for Injection USP qs

pH: 4.5 (3.5-6.5)
Calc. Osmolarity: 250 mOsmol/liter

Do not administer simultaneously with blood.

Sterile, nonpyrogenic. Single dose container.
For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNING: Some additives may be incompatible.
Consult with pharmacist. When introducing additives,

use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C).
Avoid excessive heat. See Package Insert. Rx only

Latex-free; PVC-free; DEHP-free

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Y94-003-113 LD-216-1

LOT EXP

NDC NO. 01103026415103 28

NDC 0264-1510-32
S5104-5264

100 mL Partial Fill
in 150 mL
PAB® Container

5% Dextrose Injection USP

Each mL contains:
Hydrous Dextrose USP 50 mg
Water for Injection USP qs

pH: 4.5 (3.5-6.5)
Calc. Osmolarity: 250 mOsmol/liter

Do not administer simultaneously with blood.

Sterile, nonpyrogenic. Single dose container.
For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNING: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C).
Avoid excessive heat. See Package Insert. Rx only

Latex-free; PVC-free; DEHP-free

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Y94-003-113 LD-216-1

25 50 75

PRINCIPAL DISPLAY PANEL - 50 mL Partial Fill

NDC 0264-1510-31
S5104-5384

50 mL Partial Fill
in 100 mL
PAB® Container

5% Dextrose Injection USP

Each mL contains: Hydrous Dextrose USP 50 mg; Water for Injection USP qs
pH: 4.5 (3.5-6.5) Calc. Osmolarity: 250 mOsmol/liter
Do not administer simultaneously with blood.
Sterile, nonpyrogenic. Single dose container. For intravenous use only.
Use only if solution is clear and container and seals are intact.

WARNING: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C).
Avoid excessive heat. See Package Insert. Rx Only

Latex-free; PVC-free; DEHP-free

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Y94-003-112 LD-215-1

LOT EXP

NDC NO. 01103026415103 11

NDC 0264-1510-31
S5104-5384

50 mL Partial Fill
in 100 mL
PAB® Container

5% Dextrose Injection USP

Each mL contains: Hydrous Dextrose USP 50 mg; Water for Injection USP qs
pH: 4.5 (3.5-6.5) Calc. Osmolarity: 250 mOsmol/liter
Do not administer simultaneously with blood.
Sterile, nonpyrogenic. Single dose container. For intravenous use only.
Use only if solution is clear and container and seals are intact.
WARNING: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.
Recommended Storage: Room temperature (25°C).
Avoid excessive heat. See Package Insert. Rx Only
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Y94-003-112 LD-215-1

25

PRINCIPAL DISPLAY PANEL - 25 mL Partial Fill

NDC 0264-1510-36
S5104-5410

25 mL Partial Fill
in 100 mL

PAB® Container

5% Dextrose Injection USP

Each mL contains: Hydrous Dextrose USP 50 mg; Water for Injection USP qs
pH: 4.5 (3.5-6.5) Calc. Osmolarity: 250 mOsmol/liter

Do not administer simultaneously with blood.
Sterile, nonpyrogenic. Single dose container. For intravenous use only.
Use only if solution is clear and container and seals are intact.

WARNING: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques.
Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C).
Avoid excessive heat. See Package Insert. Rx only

Latex-free; PVC-free; DEHP-free

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Y94-003-111 LD-214-1

LOT EXP

NDC NO. 01103026415103 66

NDC 0264-1510-36
S5104-5410

25 mL Partial Fill
in 100 mL
PAB® Container

5% Dextrose Injection USP

Each mL contains: Hydrous Dextrose USP 50 mg; Water for Injection USP qs
pH: 4.5 (3.5-6.5) Calc. Osmolarity: 250 mOsmol/liter

Do not administer simultaneously with blood.

Sterile, nonpyrogenic. Single dose container. For intravenous use only.
Use only if solution is clear and container and seals are intact.

WARNING: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C).
Avoid excessive heat. See Package Insert. Rx only

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[redacted] [redacted]

DEXTROSE

dextrose injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0264-1510

Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	50 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0264-1510-36	116 in 1 CASE		
1		25 mL in 1 CONTAINER		
2	NDC:0264-1510-31	84 in 1 CASE		
2		50 mL in 1 CONTAINER		
3	NDC:0264-1510-32	64 in 1 CASE		
3		100 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA016730	12/21/1973	

Labeler - B. Braun Medical Inc. (002397347)

Revised: 4/2014 B. Braun Medical Inc.