PRESCRIBING INFORMATION

70% DEXTROSE INJECTION USP

Concentrated Dextrose in Water

Solution, Intravenous

Intravenous Fluid and Nutrient Replenisher

COMPOUNDING ONLY, NOT FOR DIRECT INFUSION

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70% Dextrose Injection USP

NOT FOR DIRECT INFUSION

In Pharmacy Bulk Pack

SUMMARY PRODUCT INFORMATION

70% Dextrose Injection USP is a sterile, nonpyrogenic, hypertonic solution for fluid and nutrient replenishment in a Pharmacy Bulk Package. A Pharmacy Bulk Package is a container of sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for intravenous infusion. The solution contains no bacteriostatic or antimicrobial agents.

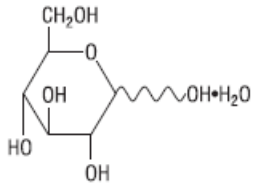
The composition, osmolarity, pH, and caloric content of 70% Dextrose Injection USP are shown in **Table 1**.

Table 1: Product Information

Product Name	DIN	Package Size (mL)	Composition (g/100 mL)* Hydrous Dextrose USP**	Osmolarity (mOsmol/L)	pH (range)	Caloric Content (kcal/L)***	Specific Gravity
70% Dextrose Injection USP	02516179	2000 mL	70	3532	4.0 (3.2 - 6.5)	2380	1.233 at 25°C

*Non-medicinal ingredient = Water for Injection (qs)
**The dextrose is purified from corn and may contain fructose.
***Calculated on the basis of 3.4 kcal/g of hydrous dextrose

The structural formula of Dextrose Hydrous is:



Flexible Plastic Container not made with natural rubber latex, PVC or DEHP.

The plastic container is made from a multilayered film specifically developed for parenteral drugs. The solution contact layer is a rubberized copolymer of ethylene and propylene. 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 use.

The container is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

ACTIONS

70% Dextrose Injection USP provides calories and is a source of water for hydration. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND CLINICAL USE

70% Dextrose Injection USP is indicated as a caloric component in a parenteral nutrition regimen in clinical conditions where enteral nutritional support is or is expected to be insufficient or impossible. This product is used with an appropriate amino acid (nitrogen) source in the prevention of nitrogen loss or in the treatment of negative nitrogen balance in patients.

CONTRAINDICATIONS

70% Dextrose Injection USP is contraindicated in the following conditions:

- Patients with hypersensitive to any ingredient in the formulation or component of the container. For a complete listing, see the **Dosage Form, Composition and Packaging** section of the Prescribing Information.
- Patients with known allergy to corn or corn products since dextrose in the product is purified from corn;
- Patients having intracranial or intraspinal hemorrhage;
- Patients who are severely dehydrated;
- Patients who are anuric, and in patients in hepatic coma;
- Patients with clinically significant hyperglycemia.

WARNINGS AND PRECAUTIONS

This injection is for compounding only, not for direct infusion.

General

70% Dextrose Injection USP should not be directly infused before appropriate dilution due to its high level of osmolarity (see **Table 1**). When diluted with an amino acid (nitrogen) source, the resultant solution should have an appropriate calorie to gram of nitrogen ratio and an osmolarity consistent with the route of administration.

Infusion of hypertonic dextrose injection into a peripheral vein may result in vein irritation, vein damage, and thrombosis. Strongly hypertonic nutrient solutions should only be administered through an indwelling intravenous catheter with the tip located in a large central vein such as the superior vena cava.

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

WARNING: 70% Dextrose Injection USP contains aluminum which 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.

This product contains no more than 25 mcg/L of aluminum.

Administration by central venous catheter should be used only by those familiar with this technique and its complications.

To reduce the risk of hypoglycemia after discontinuation, a gradual decrease in flow rate before stopping the infusion should be considered.

This product may contain fructose. Exercise caution when they are used in patients with hereditary fructose intolerance due to aldolase deficiency. In these patients, fructose may result in hypoglycemia, metabolic acidosis, liver toxicity which manifests as vomiting, nausea, sweating, jaundice, hemorrhage, seizures or coma or even death. The severity of the reactions is dependent on the amount and duration of fructose intake.

Hypersensitivity Reactions
Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, have been reported with Dextrose Injection USP (see **Adverse Reactions**).

The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Dilution and other effects on serum electrolytes
Depending on the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize dextrose, intravenous administration of dextrose can cause:

- Hyperosmolality, osmotic diuresis and dehydration
- Hypoosmolality
- Electrolyte disturbances such as
    - Hypo- or Hyperosmotic Hyponatremia
    - Hypokalemia
    - Hypophosphatemia
    - Hypomagnesemia
    - Overhydration/Hypervolemia and, for example, congested states, including pulmonary congestion and edema

Hypoosmotic Hyponatremia
Acute hyponatremia can lead to acute hyponatremic encephalopathy (brain edema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury.

The risk for developing hypoosmotic hyponatremia is increased, for example,

- in children
- in elderly patients
- in women

- postoperatively
- in persons with psychogenic polydipsia

The risk for developing encephalopathy as a complication of hypoosmotic hyponatremia is increased, for example,
- in pediatric patients (≤16 years of age)
- in women (in particular, premenopausal women)
- in patients with hypoxemia
- in patients with underlying central nervous system disease

Particular caution is advised in patients at increased risk of and from water and electrolyte disturbances that could be aggravated by increased free water load, hyperglycemia or possibly required insulin administration (see below).

Preventive and corrective measures must be instituted as clinically indicated.

Hyperglycemia
As with the intravenous administration of nutrients (e.g., glucose, amino acids and lipids) in general, metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed. Adverse metabolic effects may arise from administration of inadequate or excessive nutrients or from inappropriate composition of an admixture for a particular patient's needs.

Rapid administration of dextrose-containing solutions may produce substantial hyperglycemia which may result in or contribute to electrolyte losses, dehydration and hypovolemia due to osmotic diuresis and a hyperosmolar syndrome. At certain clinical conditions it also may increase the risk of hypoosmotic hyponatremia by shifting of intracellular water to extracellular space, resulting in serious clinical outcomes (see text under the subheading "Hypoosmotic hyponatremia" in this section).

Use with caution in critically ill patients in whom hyperglycemia commonly occurs due to diabetes, impaired glucose tolerance, impaired fasting glucose, or is stress-induced.

Hyperglycemia may increase the risk of cardiac complications, infection, systemic sepsis, acute renal failure and even death in certain clinical conditions, especially in acute stress conditions.

In order to avoid hyperglycemia the infusion rate should not exceed the patient's ability to utilize glucose.

To reduce the risk of hyperglycemia-associated complications, the infusion rate must be adjusted to the level suitable to the patient's ability to utilize glucose and/or insulin administered if blood glucose levels exceed levels considered acceptable for the individual patient.

Intravenous dextrose should be administered with caution in patients with, for example:
- impaired glucose tolerance (such as in diabetes mellitus, renal impairment, or in the presence of sepsis, trauma, or shock)
- severe malnutrition (risk of precipitating a refeeding syndrome)
- thiamine deficiency, e.g., in patients with chronic alcoholism (risk of severe lactic acidosis due to impaired oxidative metabolization of pyruvate)

- water and electrolyte disturbances that could be aggravated by increased glucose and/or free water load (see above)
- patients with ischemic stroke. Hyperglycemia has been implicated in increasing cerebral ischemic brain damage and impairing recovery after acute ischemic strokes.
- patients with severe traumatic brain injury (in particular during the first 24 hours following the trauma). Early hyperglycemia has been associated with poor outcomes in patients with severe traumatic brain injury.
- Newborns (see **Special Populations, Pediatrics**)

Prolonged intravenous administration of dextrose and associated hyperglycemia may result in decreased rates of glucose-stimulated insulin secretion.

Refeeding Syndrome
Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications.

Liver Disorders
Hepatobiliary disorders including cholestasis, hepatic steatosis, fibrosis and cirrhosis, possibly leading to hepatic failure, as well as cholecystitis and cholelithiasis are known to develop in some patients on parenteral nutrition. The etiology of these disorders is thought to be multifactorial and may differ between patients. Patients developing abnormal laboratory parameters or other signs of hepatobiliary disorders should be assessed early by a clinician knowledgeable in liver diseases in order to identify possible causative and contributory factors, and possible therapeutic and prophylactic interventions.

Catheter infection and sepsis
Infection and sepsis may occur as a result of the use of intravenous catheters to administer parenteral formulations, poor maintenance of catheters or contaminated solutions.

Immunosuppression and other factors such hyperglycemia, malnutrition and/or their underlying disease state may predispose patients to infectious complications.

Careful symptomatic and laboratory monitoring for fever/chills, leukocytosis, technical complications with the access device, and hyperglycemia can help recognize early infections.

The occurrence of septic complications can be decreased with heightened emphasis on aseptic technique in catheter placement, maintenance, as well as aseptic technique in nutritional formula preparation.

Precipitates
Pulmonary vascular precipitates have been reported in patients receiving parenteral nutrition. In some cases, fatal outcomes have occurred. Excessive addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates. Precipitates have been reported even in the absence of phosphate salt in the solution. Precipitation distal to the in-line filter and suspected precipitate formation in the blood stream has also been reported.

In addition to inspection of the solution, the infusion set and catheter should also periodically be checked for precipitates.

If signs of pulmonary distress occur, the infusion should be stopped and medical evaluation initiated.

Administration of hypertonic dextrose and amino acid solutions via central venous catheter may be associated with complications which can be prevented or minimized by careful attention to all aspects of the procedure. This includes attention to solution preparation, administration and patient monitoring.

It is essential that a carefully prepared protocol, based upon current medical practice, be followed, preferably by an experienced team.

The package insert of the protein (nitrogen) source should be consulted for dosage and all precautionary information.

Care should be taken to avoid circulatory overload, particularly in patients with cardiac insufficiency.

70% Dextrose Injection USP should be used with caution in patients with overt or subclinical diabetes mellitus.

70% Dextrose Injection USP (an aqueous, i.e., electrolyte-free dextrose solution) should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis.

Risk of Air Embolism
Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Monitoring and Laboratory Tests
Clinical evaluation and periodic laboratory determination are necessary to monitor changes in plasma glucose level, fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

Monitoring of serum sodium is particularly important. High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including Syndrome of Inappropriate Antidiuretic Hormone Secretion (SIADH)), due to the risk of hospital-acquired hyponatremia.

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

Special Populations

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

Nursing Mothers: Caution should be exercised when Dextrose Injection USP is administered to a nursing woman.

Intrapartum maternal intravenous dextrose infusion may result in fetal insulin production, with an associated risk of fetal hyperglycemia and metabolic acidosis as well as rebound hypoglycemia in the neonate.

Healthcare practitioners should carefully consider the potential risks and benefits for each specific patient before administering.

Pediatrics
Due to hypertonicity, the dextrose injection must be diluted prior to administration.

The infusion rate and volume depend on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in pediatric intravenous fluid therapy.

Pediatric Glycemia-related Issues
Newborns – especially those born premature and with low birth weight, are at increased risk of developing hypo- or hyperglycemia. Close monitoring during treatment with intravenous dextrose solutions is needed to ensure adequate glycaemic control, in order to avoid potential long term adverse effects.

HYPOglycemia in the newborn can cause:
- Prolonged seizures
- coma, and
- cerebral injury

HYPERglycemia has been associated with
- cerebral injury, including intraventricular hemorrhage,
- late onset bacterial and fungal infection,
- retinopathy of prematurity,
- necrotizing enterocolitis,
- bronchopulmonary dysplasia
- increased oxygen requirements,
- prolonged length of hospital stay, and
- death

Pediatric Hyponatremia-related Issues
Children (including neonates and older children) are at increased risk of developing hypoosmotic hyponatremia as well as for developing hyponatremic encephalopathy. Acute hyponatremia can lead to acute hyponatremic encephalopathy (brain edema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury.

Plasma electrolyte concentrations should be closely monitored in the pediatric population.

Rapid correction of hypoosmotic hyponatremia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a physician experienced in pediatric intravenous fluid therapy.

Geriatrics
When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases or concomitant drug therapy.

ADVERSE REACTIONS

Too rapid infusion of a hypertonic dextrose solution may result in diuresis, hyperglycemia, glycosuria and hyperosmolar coma. Continual clinical monitoring of the patient is necessary in order to identify and initiate measures for these clinical conditions.

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.

Anaphylactic reaction, hypersensitivity, pyrexia, and chills have also been reported.

The list of adverse reactions in this Prescribing Information is based on postmarketing reports (see below).

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.

Post-marketing Adverse Reactions
The following adverse reactions have been reported in the post-marketing experience, listed by MedDRA System Organ Class (SOC), then, where feasible, by Preferred Term in order of severity.

IMMUNE SYSTEM DISORDERS: Hypersensitivity/infusion reactions, including Anaphylactic/ Anaphylactoid reactions, including reactions with mild manifestations, e.g., Pruritus, and reactions with severe manifestations, e.g., Bronchospasm, Cyanosis, Angioedema and Hypotension; Pyrexia, Chills

METABOLISM AND NUTRITION DISORDERS: Hyperglycemia

SKIN AND SUBCUTANEOUS TISSUE DISORDERS: Rash

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: Infusion site reactions including, Infusion site phlebitis, Infusion site erythema.

Other adverse reactions reported with dextrose injection/infusions include:

- Hyponatremia, which may be symptomatic (see under the subheading "Hypoosmotic hyponatremia" in **Warnings and Precautions**).
- Hyponatremic encephalopathy
- Infusion site thrombophlebitis (associated with hyperosmolar solutions).
- Adverse reactions reported with parenteral nutrition to which the dextrose component may play a causal or contributory role include:
    - Hepatic failure, Hepatic cirrhosis, Hepatic fibrosis, Cholestasis, Hepatic steatosis, Blood bilirubin increased, Hepatic enzyme increased, Cholecystitis, Cholelithiasis
    - Pulmonary vascular precipitates

DRUG INTERACTIONS

No studies have been conducted by B. Braun Medical Inc.

Caution must be exercised in the administration of the injection to patients receiving corticosteroids or corticotropin.

Both the glycemic effects of Dextrose Injection USP and its effects on water and electrolyte balance should be taken into account when using Dextrose Injection USP in patients treated with other substances that affect glycemic control, or fluid and/or electrolyte balance.

Caution is advised when administering Dextrose Injection USP to patients treated with drugs leading to an increased vasopressin effect. The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hyponatremia following treatment with i.v. fluids.

- Drugs stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3.4- methylenedioxy-N-methamphetamine, ifosfamide, antipsycotics, opioids.
- Drugs potentiating vasopressin action such as chlorpropamide, non steroidal anti-inflammatories (NSAIDS), cyclophosphamide.
- Vasopressin analogues such as desmopressin, oxytocin, vasopressin, terlipressin.

Caution is advised when administering Dextrose Injection USP to patients treated with drugs that may increase the risk of hyponatremia, such as diuretics and antiepileptics (e.g., oxcarbazepine).

DOSAGE AND ADMINISTRATION

Following suitable admixture of prescribed drugs, the dosage is usually dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations. See directions accompanying drugs.

As reported in the literature, the dosage selection 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.

Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants. The infusion rate and volume depend on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in pediatric intravenous fluid therapy.

A gradual increase of flow rate should be considered when starting administration of dextrose-containing products.

Electrolyte supplementation may be indicated according to the clinical needs of the patient.

As indicated on an individual basis, vitamins and trace elements and other components (including amino acids and lipids) can be added to the parenteral regimen to meet nutrient needs and prevent deficiencies and complications from developing.

70% Dextrose Injection USP in the Pharmacy Bulk Package are intended for use in the preparation of sterile, intravenous admixtures.

Additives may be incompatible. Complete information is not available. When introducing additives to Dextrose Injection USP, the instructions for use of the medication to be added and other relevant literature must be consulted.

Those additives known to be incompatible with the product should not be used. Consult with pharmacist if available. If in the informed judgment of the physician it is deemed advisable to introduce additives, aseptic technique must be used.

Before adding a substance or medication, verify that it is soluble and/or stable in dextrose and that the pH range of Dextrose Injection USP is appropriate.

After addition, check for a possible color change and/or the appearance of precipitates, insoluble complexes or crystals.

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

Do not administer unless solution is clear and the seal is intact.

70% Dextrose Injection USP in the Flexible Plastic Container is intended for intravenous administration using sterile equipment.

Use of an in-line filter is recommended during administration of all parenteral solutions where possible.

Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

OVERDOSAGE

Excess administration of 70% Dextrose Injection USP can cause hyperglycemia, adverse effects on water and electrolyte balance, and corresponding complications (see **Warnings and Precautions** and **Adverse Reactions**). For example, severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal.

Interventions include discontinuation of 70% Dextrose Injection USP administration, dose reduction, administration of insulin and other measures as indicated for the specific clinical constellation.

Clinically significant overdose of 70% Dextrose Injection USP may, therefore, constitute a medical emergency.

DOSAGE FORM, COMPOSITION AND PACKAGING

How supplied

Table 1 shows the composition, osmolarity, approximate pH, calories/litre and available size of 70% Dextrose Injection USP.

70% Dextrose Injection USP is supplied in 2000 mL Pharmacy Bulk Package containers, packaged 4 per case.

Directions for use of Pharmacy Bulk Package Container

Caution: Do not use plastic containers in series connection.

70% Dextrose Injection USP in the Pharmacy Bulk Package is intended for use in the preparation of sterile, intravenous admixtures.

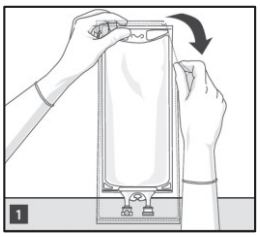
Refer to standard texts and guidelines on the preparation of parenteral nutritional admixtures.

When compounding admixtures, use aseptic technique. Mix thoroughly. Do not store any unused portion of 70% Dextrose Injection USP. Discard container within 4 hours of entering closure.

To open:

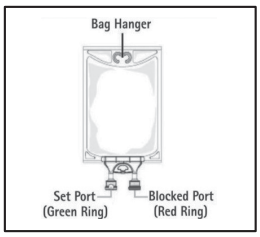
1. Inspect overwrap. Do not use if overwrap has been damaged.
2. Do not use unless solution is clear and closure is intact.
3. Tear overwrap starting from the tear notches (see **Figure 1**).
4. Inspect the container for minute leaks by squeezing inner bag firmly. If leaks are found, discard the bag as sterility may be impaired.
5. For compounding only. Do no use for direct infusion.

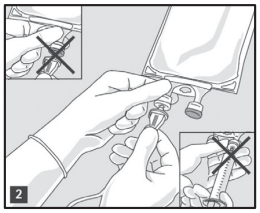
Preparation for Admixing:



Note: Important Admixing Instructions

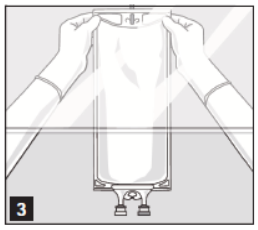
- **The Pharmacy Bulk Package is to be used only in a suitable work area such as a laminar airflow hood (or an equivalent clean air compounding area).**
- The contents are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes.
- Additives may be incompatible with the fluid withdrawn from this container. When compounding admixtures, use aseptic technique, mix thoroughly and do not store.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution container permits (see **Dosage and Administration**).





1. Do not use/penetrate blocked port (see **Figure 2**, left upper corner).
2. Remove aluminum foil of set port at the bottom of container.
3. Attach suitable transfer device or compounding set (**Figure 2**). Refer to complete directions accompanying device.

   Note: The closure shall be penetrated only one time with a suitable sterile transfer device or dispensing set which allows measured dispensing of the contents.



4. The container should not be written on directly since ink migration has not been investigated. Affix accompanying label for date and time of entry notation.
5. Hang bag on suitable fixture (see **Figure 3**).
6. Once container closure has been penetrated, withdrawal of content should be completed within 4 hours while maintaining contents at 15-25°C.

STORAGE

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. 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.

If you want more information about 70% Dextrose Injection USP:

- Talk to your healthcare professional
- Find the full prescribing information that is prepared for healthcare professionals by visiting the Drug Product Database (*https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html* or by calling 1-800-854-6851.

This Prescribing Information was prepared by:

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