PRESCRIBING INFORMATION

# Dextrose Injection USP

(Concentrated Dextrose for Intravenous Administration)

**50%**
(500 mg/mL)

Fluid and Nutrient Replenisher

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(Concentrated Dextrose for Intravenous Administration)

**50%**
(500 mg/mL)

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**NOTE:** This solution is hypertonic—see **WARNINGS** and **PRECAUTIONS**

## ACTION AND 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 or glycogen depletion and exerts a protein-sparing action. Dextrose injection undergoes oxidation to carbon dioxide and water.

## INDICATIONS AND CLINICAL USE

Dextrose Injection USP is indicated in the treatment of insulin hypoglycemia (hyperinsulinism 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 pseudo-agglutination of red cells may occur.

## WARNINGS

Dextrose Injection USP is hypertonic and may cause phlebitis and thrombosis at the site of injection. Significant hyperglycemia and possible hyperosmolar syndrome may result from a too rapid administration. The physician should be aware of the symptoms of hyper-osmolar 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 electrolytes, overhydration, congested states or pulmonary edema.

The risk of dilutional states is inversely proportional to electrolyte concentrations of administered parenteral solutions.

Care should be taken to avoid hyperglycemia in patients with acute ischemic strokes, as hyperglycemia has been implicated in increasing cerebral ischemic brain damage and in impairing recovery.

Additives may be incompatible. Consult with a pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

### Peripheral Vein Administration

The solution should be given slowly, preferably through a small bore needle into a large vein, to minimize venous irritation.

### Central Venous Administration

Concentrated dextrose should be administered via central vein only after suitable dilution.

## 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 should also be provided as needed.

Hyperglycemia and consequently glycosuria may occur with excessive administration. 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 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.

**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 the benefits outweigh the risks.

## ADVERSE REACTIONS

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

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

**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 at a rate of 0.8 g/kg/hr.

In insulin-induced hypoglycemia, intravenous injection of 10 to 25 g 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.

**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 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.

## STORAGE RECOMMENDATIONS

Product should be stored between 20 to 25°C. Protect from freezing and excessive heat.

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

Do not use unless solution is clear and container or seal intact. Discard if it contains a precipitate.

Single-use; discard unused portion.

## AVAILABILITY

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit. Do not use unless the solution is clear and seal is intact. Discard unused portion.

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 100 mL of fluid contains 50 g of dextrose hydrous which delivers 3.4 kcal/g. The solution has an osmolarity of 2526 mOsm/L (calc.), an approximate pH of 4.2 and may contain sodium hydroxide and 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-use injection. When smaller doses are required, the unused portion should be discarded with the entire unit.

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

| Container | Size |
|---|---|
| 50 mL Fliptop Vial | 25 g in 50 mL |
| LifeShield ™ Abboject ™ Syringe[1] | 25 g in 50 mL |
| Ansyr ™ II Syringe[2] | 25 g in 50 mL |

**1: LifeShield ™ Abboject ™ syringes**: Flexible and reliable, the ready-to-use LifeShield™ Abboject™ syringe minimizes errors and protects caregivers and patients alike. It can be used for needle-free or shrouded needle access. The design features

two pieces — a calibrated glass drug vial and a matching plastic syringe barrel with integral injector needle. Medication, fluid path and needle are sterile and nonpyrogenic if caps and needle cover are undisturbed and package intact.

**2:Ansyr** $^{TM}$ II **Syringe**: The Ansyr™ II syringe is a proprietary delivery option offering the combination of drugs and an innovative delivery systems with syringe and barrel detached, polypropylene plastic construction with a needle-free male luer lock adapter. Ansyr™ II syringes are available prefilled with a wide range of emergency medications. Graduated markings on the syringe barrel conform to ISO standards and clearly show any drug remaining. Medication and fluid path are sterile and nonpyrogenic if protective cover is undisturbed and package intact.