DEXTROSE- dextrose monohydrate injection, solution
Baxter Healthcare Corporation

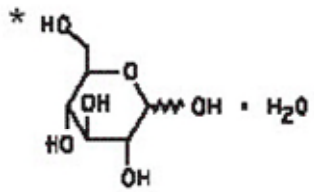
Dextrose Injection, USP in VIAFLO Plastic Container

DESCRIPTION

Dextrose Injection, USP is a sterile, nonpyrogenic solution for fluid replenishment and caloric supply in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, and caloric content are shown in Table 1.

Table 1

	Size (mL)	* Dextrose Hydrous, USP (g/L)	Osmolarity (mOsmol/L) (calc.)	pH	Caloric Content (kcal/L)
5% Dextrose Injection, USP	250 500 1000	50	252	4.0 (3.2 to 6.5)	170



D-Glucose monohydrate

VIAFLO is a flexible plastic container fabricated from a multilayer sheeting (PL-2442) composed of Polypropylene (PP), Polyamide (PA) and Polyethylene (PE). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Two different administration connectors are available with VIAFLO containers. The VIAFLO dripless access container (DAC) will not drip once the spike is removed. The non-DAC VIAFLO will drip once the spike is removed from the administration port.

VIAFLO is not made with natural rubber latex, DEHP, or PVC.

CLINICAL PHARMACOLOGY

Dextrose Injection, USP has value as a source of water and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE

Dextrose Injection, USP is indicated as a source of water and calories.

CONTRAINDICATIONS

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

WARNINGS

Dextrose Injection, USP should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis.

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. The risk of dilutive states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Excessive administration of dextrose injections may result in significant hypokalemia.

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

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.

PRECAUTIONS

General

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

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.

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

Pregnancy

There are no adequate and well controlled studies with Dextrose Injection, USP in pregnant women and animal reproduction studies have not been conducted with this drug. Therefore, it is not known whether Dextrose Injection, USP can cause fetal harm when administered to a pregnant woman. Dextrose Injection, USP should be given during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery

Intrapartum maternal intravenous infusion of glucose-containing solutions may produce maternal hyperglycemia with subsequent fetal hyperglycemia and fetal metabolic acidosis. Fetal hyperglycemia can result in increased fetal insulin levels which may result in neonatal hypoglycemia following delivery. Consider the potential risks and benefits for each specific patient before administering Dextrose Injection, USP.

Nursing Mothers

It is not known whether this drug is present in human milk. Because many drugs are present in human milk, caution should be exercised when a Dextrose Injection, USP is administered to a nursing woman.

Pediatric Use

The use of Dextrose Injection, USP in pediatric patients is based on clinical practice (see **DOSAGE AND ADMINISTRATION**).

Newborns – especially those born premature and with low birth weight - are at increased risk of developing hypo- or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycemic control in order to avoid potential long term adverse effects. Hypoglycemia in the newborn can cause prolonged seizures, coma and brain damage. Hyperglycemia has been associated with intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

Geriatric Use

Clinical studies of Dextrose Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified 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

Hypersensitivity reactions, including anaphylaxis and chills.

Reactions which may occur because of the injection 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.

DOSAGE AND ADMINISTRATION

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

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions, where possible.

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

All injections in VIAFLO plastic containers are intended for intravenous administration using sterile equipment.

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 depends 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.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

The available sizes of each Dextrose Injection, USP in VIAFLO dripless access containers (DAC) and non-DAC plastic containers are shown below. VIAFLO DAC will not drip once the spike is removed. VIAFLO non-DAC will drip once the spike is removed from the administration port:

Code	Size(mL)	Product	NDC
UE0062D	250	DAC	0338-0062-30
UE0062	250	Non-DAC	0338-0074-30

UE0063D	500	DAC	0338-0066-20
UE0063	500	Non-DAC	0338-0078-20
UE0064D	1000	DAC	0338-0070-10
UE0064	1000	Non-DAC	0338-0082-10

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F); brief exposure up to 40°C/104°F does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLO PLASTIC CONTAINER

For Information on Risk of Air Embolism - see **PRECAUTIONS**

To Open

Tear overwrap down side at slit and remove solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

1. Remove the container from the over wrap just before use.
2. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired.
3. Check solution for clarity and absence of foreign matter. If solution is not clear or contains foreign matter, discard the solution.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
   Grip the small wing on the neck of the port with one hand,
   grip the large wing on the cap with the other hand and twist,
   the cap will pop off.
3. Use an aseptic method to set up the infusion.
4. Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, tap ports gently while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by tapping them gently while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in-use position and continue administration.

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

SA-30-02-294

Rev. March 2019