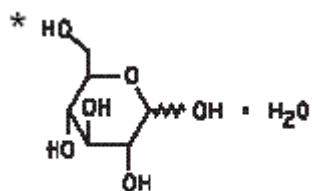


Dextrose Injection, USP in AVIVA Plastic Container DESCRIPTION

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 nominal (range)	Caloric Content (kcal/L)
5% Dextrose Injection, USP	250 500 1000	50	252	4.5 (3.2 to 6.5)	170
10% Dextrose Injection, USP	250 500 1000	100	505	4.5 (3.2 to 6.5)	340



D-Glucose monohydrate

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (see **DIRECTIONS FOR USE**). The primary function of the overwrap is to protect the container from the physical environment.

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.

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.

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 a 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

Pregnancy Category C

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 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 AVIVA 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

Dextrose Injection, USP in AVIVA plastic container is available as follows:

Code	Size (ml)	NDC	Product Name
6E0062	250	0338-6346-02	5% Dextrose Injection, USP
6E0063	500	0338-6346-03	
6E0064	1000	0338-6346-04	
6E0162	250	0338-6347-02	10% Dextrose Injection, USP
6E0163	500	0338-6347-03	
6E0164	1000	0338-6347-04	

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 AVIVA 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 “**To Add Medication**” directions below.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.

3. Attach administration set. Refer to complete directions accompanying set.

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, squeeze ports 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 squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in-use position and continue administration.

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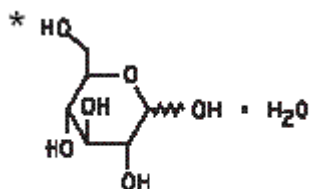
Dextrose Injection, USP in VIAFLEX Plastic Container

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	25 Quad pack	50	252	4.0 (3.2 to 6.5)	170
	50 Single pack Quad pack Multi pack				
10% Dextrose Injection, USP	100 Single pack Quad pack Multi pack	100	505	4.0 (3.2 to 6.5)	340
	250 500 1000				



D-Glucose monohydrate

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological test for plastic containers as well as by tissue culture toxicity studies.

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

Pregnancy Category C

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 VIAFLEX 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

Dextrose Injection, USP in VIAFLEX plastic container is available as follows:

Code	Size	(mL)	NDC	Product Name
	25			
2B0080		Quad pack	0338- 0017- 10	5% Dextrose Injection, USP
	50			
2B0086		Single pack	0338-0017-41	5% Dextrose Injection, USP
2B0081		Quad pack	0338-0017-11	
2B0088		Multi pack	0338-0017-31	
	100			
2B0087		Single pack	0338-0017-48	5% Dextrose Injection, USP
2B0082		Quad pack	0338-0017-18	
2B0089		Multi pack	0338-0017-38	
2B0061	150		0338- 0017-01	
2B0062	250		0338- 0017-02	
2B0063	500		0338- 0017-03	
2B0064	1000		0338- 0017-04	
2B0162	250		0338- 0023-02	10% Dextrose Injection, USP
2B0163	500		0338- 0023-03	
2B0164	1000		0338- 0023-04	

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 VIAFLEX 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 “**To Add Medication**” directions below.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

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, squeeze ports 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 squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in-use position and continue administration.

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70% Dextrose Injection, USP

in VIAFLEX Plastic Container

A Parenteral Nutrient

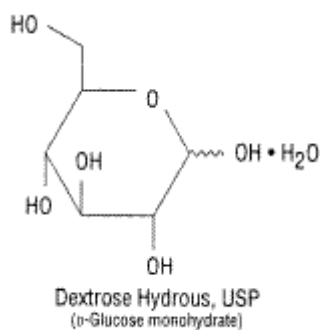
DESCRIPTION

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

Table 1

	Composition	Osmolarity (mOsmol/L) (calc.)	pH	Caloric Content (kcal/L)	How Supplied
	Dextrose Hydrous, USP (g/L)				Size
					500 mL in 1000 mL container
					Code and NDC
70% Dextrose Injection, USP	700	3530	4.0 (3.2 to 6.5)	2390	2B0114 NDC 0338-0719-13

The structural formula of Dextrose Hydrous, USP is:



The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). 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. The amount of water that can permeate from inside the container into the overwrap is insufficient 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.

CLINICAL PHARMACOLOGY

Dextrose Injection, USP have value as a source of water and calories. They are capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE

Dextrose Injection, USP are indicated as a caloric component in a parenteral nutrition regimen. They are used with an appropriate protein (nitrogen) source in the prevention of nitrogen loss or in the treatment of negative nitrogen balance in patients where: (1) the alimentary tract cannot or should not be used, (2) gastrointestinal absorption of protein is impaired, or (3) metabolic requirements for protein are substantially increased, as with extensive burns.

CONTRAINDICATIONS

The infusion of hypertonic dextrose injection is contraindicated in patients having intracranial or intraspinal hemorrhage, in patients who are severely dehydrated, in patients who are anuric, and in patients in hepatic coma.

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

WARNINGS

Dilute before use to a concentration which will, when administered with an amino acid (nitrogen) source, result in an appropriate calorie to gram of nitrogen ratio and which has an osmolarity consistent with the route of administration.

Unless appropriately diluted, the 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: 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.

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.

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 medical 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.

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

These injections should be used with caution in patients with overt or subclinical diabetes mellitus.

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

Pregnancy

Pregnancy Category C

There are no adequate and well controlled studies with Dextrose Injections, USP in pregnant women and animal reproduction studies have not been conducted with this drug. Therefore, it is not known whether Dextrose Injections, USP can cause fetal harm when administered to a pregnant woman. Dextrose Injections, 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 if this drug is present in human milk. Because many drugs are present in human milk, caution should be exercised when Dextrose Injection, USP, is administered to a nursing woman.

Pediatric Use

The use of Dextrose in pediatric patients is based on clinical practice (see **DOSAGE AND ADMINISTRATION**). Because of their hypertonicity, 70% Dextrose Injection must be diluted prior to 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.

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.

Hypersensitivity reactions, including anaphylaxis and chills.

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.

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.

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.

These admixed injections in VIAFLEX 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 judgement 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

See Table 1.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended the product be stored at room temperature (25°C/77°F).

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

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

Preparation for Administration

1. 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.

2. Insert transfer set into prepared solution container to be transferred. Follow directions accompanying transfer set.
3. Remove protector from extended middle port of dextrose solution container and insert connector of transfer set.
4. Transfer solution by gravity or by using a VIAVAC unit.
5. After desired solution has been transferred, mix thoroughly and seal extension tubing of extended middle port. Cut between seal and connector of transfer set.
6. Check for leaks.
7. **Warning:** Additives may be incompatible. Supplemental medication may be added with a 19 to 22 gauge needle through the medication injection site on the dextrose solution container. Mix solution and medication thoroughly. For high density medications, such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.
8. Suspend container from eyelet support.
9. Remove plastic protector from outlet port at bottom of container.
10. Attach administration set. Refer to complete directions accompanying set.

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50% and 70% Dextrose Injection, USP

**Pharmacy Bulk Package
Not for Direct Infusion**

VIAFLEX Plastic Container A Parenteral Nutrient

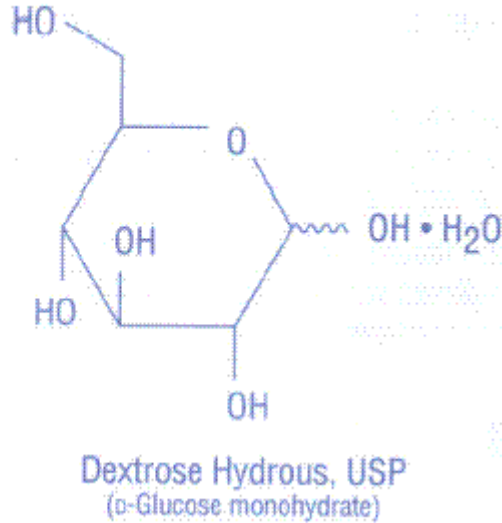
DESCRIPTION

Dextrose Injections, USP are sterile, nonpyrogenic hypertonic solutions for fluid replenishment and caloric supply in 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. They contain no antimicrobial agents. Composition, osmolarity, pH, and caloric content are shown below.

Table 1.

	Composition	Osmolarity (mOsmol/L) (calc.)	pH	Caloric Content (kcal/L)	How Supplied
	Dextrose Hydrous, USP (g/L)				Size, code, NDC
					2000 mL unit
50% Dextrose Injection, USP	500	2520	4.0 (3.2 to 6.5)	1710	2B0256 NDC 0338-0031-06
70% Dextrose Injection, USP	700	3530	4.0 (3.2 to 6.5)	2390	2B0296 NDC 0338-0719-06

The structural formula of Dextrose Hydrous, USP is:



The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). 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. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly.

Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

Dextrose Injection, USP have value as a source of water and calories. They are capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE

Dextrose Injection, USP are indicated as a caloric component in a parenteral nutrition regimen. They are used with an appropriate protein (nitrogen) source in the prevention of nitrogen loss or in the treatment of negative nitrogen balance in patients where: (1) the alimentary tract cannot or should not be used, (2) gastrointestinal absorption of protein is

impaired, or (3) metabolic requirements for protein are substantially increased, as with extensive burns.

CONTRAINDICATIONS

The infusion of hypertonic dextrose injections is contraindicated in patients having intracranial or intraspinal hemorrhage, in patients who are severely dehydrated, in patients who are anuric, and in patients in hepatic coma.

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

WARNINGS

These injections are for compounding only, not for direct infusion.

Dilute before use to a concentration which will, when administered with an amino acid (nitrogen) source, result in an appropriate calorie to gram of nitrogen ratio and which has an osmolarity consistent with the route of administration.

Unless appropriately diluted, the 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: 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.

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

Monitor changes in fluid balance, electrolyte concentration, and acid base balance during prolonged parenteral therapy or whenever the conditions of the patient warrants such evaluation.

PRECAUTIONS

General

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 medical team.

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

Monitor changes in fluid balance, electrolyte concentration, and acid base balance during prolonged parenteral therapy or whenever the conditions of the patient warrants such evaluation.

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

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

These injections should be used with caution in patients with overt or subclinical diabetes mellitus.

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

Pregnancy

Pregnancy Category C

There are no adequate and well controlled studies with Dextrose Injections, USP in pregnant women and animal reproduction studies have not been conducted with this drug. Therefore, it is not known whether Dextrose Injections, USP can cause fetal harm when

administered to a pregnant woman. Dextrose Injections, 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 Injections, 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 50% and 70% Dextrose Injection, USP is administered to a nursing woman.

Pediatric Use

The use of Dextrose in pediatric patients is based on clinical practice (see **DOSAGE AND ADMINISTRATION**). Because of their hypertonicity, 50% and 70% Dextrose Injections must be diluted prior to 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.

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.

Hypersensitivity reactions, including anaphylaxis and chills.

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.

DOSAGE AND ADMINISTRATION

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

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 seal is intact.

Use of a final filter is recommended during administration of all parenteral solutions where possible.

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.

50% and 70% Dextrose Injection, USP in the Pharmacy Bulk Package is intended for use in the preparation of sterile, intravenous admixtures. Additives may be incompatible with the fluid withdrawn from this container. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. When compounding admixtures, use aseptic technique. Mix thoroughly. Do not store any unused portion of the 50% and 70% Dextrose Injection, USP.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC PHARMACY BULK PACKAGE CONTAINER

To Open

Tear overpouch 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.

For compounding only, not for direct infusion.

Preparation for Admixing

1. The Pharmacy Bulk Package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).
2. Suspend container from eyelet support.
3. Remove plastic protector from outlet port at bottom of container.
4. Attach solution transfer set. Refer to complete directions accompanying set.
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.
5. The VIAFLEX plastic container should not be written on directly since ink migration has not been investigated. Affix accompanying label for date and time of entry notation.
6. Once container closure has been penetrated, withdrawal of contents should be completed without delay. After initial entry, maintain contents at room temperature (25°C/77°F) and dispense within 4 hours.

HOW SUPPLIED

See Table 1.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended the product be stored at room temperature (25°C/77°F).

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