

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

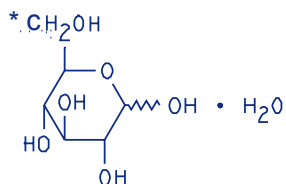
Page 136

Baxter

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in AVIVA Plastic Container

Description

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. Each 100 mL contains 5 g Dextrose Hydrous, USP*, 260 mg Sodium Lactate (C₃H₅NaO₃), 141 mg Potassium Chloride, USP (KCl), 31 mg Magnesium Chloride, USP (MgCl₂•6H₂O), 20 mg Monobasic Potassium Phosphate, NF (KH₂PO₄), and 12 mg Sodium Chloride, USP (NaCl). It contains no antimicrobial agents. pH 5.0 (4.0 to 6.5).



D-Glucopyranose monohydrate

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 25 mEq sodium, 20 mEq potassium, 3 mEq magnesium, 24 mEq chloride, 23 mEq lactate and 3 mEq phosphate as HPO₄⁻. The osmolarity is 348 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage. The caloric content is 180 kcal/L.

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.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

Page 137

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

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) has value as a source of water, electrolytes and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) produces a metabolic alkalinizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is indicated as a source of water, electrolytes, and calories or as an alkalinizing agent.

Contraindications

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

Warnings

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

Page 138

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, 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 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) may result in sodium or potassium retention.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is not for use in the treatment of lactic acidosis.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one 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.

Do not administer simultaneously with blood.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

Page 139

Drug Interactions

Caution must be exercised in the administration of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP).

Carcinogenesis, mutagenesis, impairment of fertility

Studies with 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP). It is also not known whether 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of dextrose and electrolytes solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

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

Geriatric Use

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

Page 140

Clinical studies of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, 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 the responses between 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 drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

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. 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.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

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.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

Page 141

How Supplied

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in AVIVA plastic containers is available as shown below:

Code	<u>Size (mL)</u>	NDC
6E2102	250	NDC 0338-6322-02
6E2103	500	NDC 0338-6322-03
6E2104	1000	NDC 0338-6322-04

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

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and 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.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

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.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

Page 142

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.

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

Printed in USA

* Bar Code Position Only

XXXXXXXXXX

©Copyright XXXX Baxter Healthcare Corporation

All rights reserved.

X-XX-XX-XXX

Rev. August 2005

Baxter and AVIVA are trademarks of Baxter International Inc.