

NORMOSOL-M AND DEXTROSE- dextrose monohydrate, sodium chloride, potassium acetate, and magnesium acetate injection, solution
ICU Medical Inc.

NORMOSOL™ -M and 5% DEXTROSE Injection
MULTIPLE ELECTROLYTES AND 5% DEXTROSE INJECTION TYPE 1, USP

Flexible Plastic Container

Rx Only

DESCRIPTION

Normosol-M and 5% Dextrose Injection (Multiple Electrolytes and 5% Dextrose Injection Type 1, USP) is a sterile, nonpyrogenic, hypertonic solution of balanced maintenance electrolytes and 5% dextrose injection in water for injection.

The solution is administered by intravenous infusion for parenteral maintenance of routine daily fluid and electrolyte requirements with minimal carbohydrate calories.

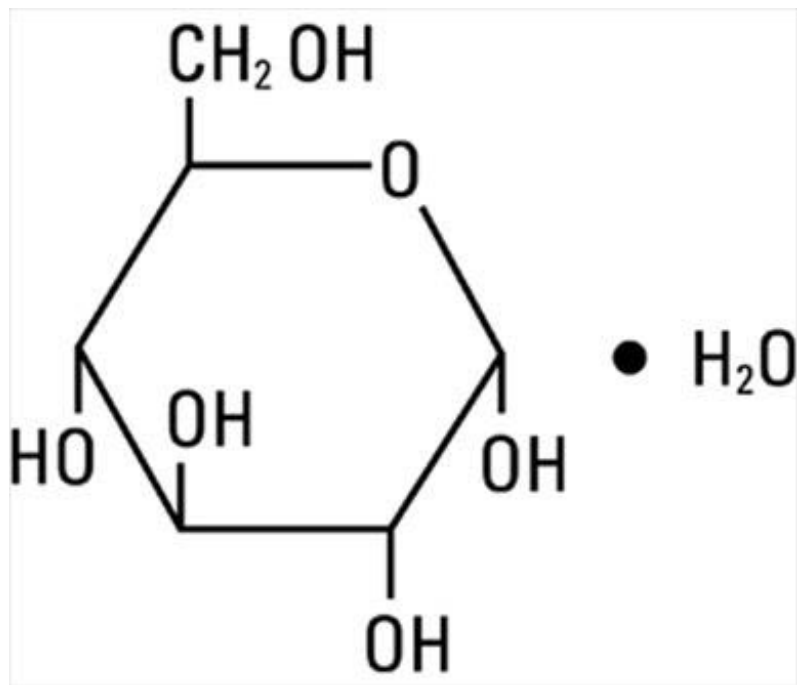
Each 100 mL contains dextrose, hydrous 5 g, sodium chloride, 234 mg, potassium acetate, 128 mg and magnesium acetate, anhydrous 21 mg. May contain hydrochloric acid for pH adjustment. The electrolyte content (not including hydrochloric acid) and other characteristics are as follows:

Sodium (Na ⁺)	40 mEq/liter
Potassium (K ⁺)	13 mEq/liter
Magnesium (Mg ⁺⁺)	3 mEq/liter
Chloride (Cl ⁻)	40 mEq/liter
Bicarbonate (HCO ₃ ⁻) as acetate	16 mEq/liter
Caloric value (dextrose)	170 Calories/liter
Tonicity	Hypertonic
Osmolarity	363 mOsmol/liter (calc.)
pH (range)	5.0 (4.0 to 6.5)

The solution contains no bacteriostat, antimicrobial agent or added buffer (except for pH adjustment) and is intended only for use as a single-dose injection. When smaller doses are required the unused portion should be discarded.

Normosol-M and 5% Dextrose Injection is a parenteral fluid, electrolyte and nutrient replenisher.

Dextrose, USP is chemically designated D-glucose monohydrate (C₆H₁₂O₆ • H₂O), a hexose sugar freely soluble in water. It has the following structural formula:



Sodium Chloride, USP is chemically designated NaCl , a white crystalline powder freely soluble in water.

Potassium Acetate, USP is chemically designated CH_3COOK , colorless crystals or white crystalline powder very soluble in water.

Magnesium acetate is chemically designated $\text{Mg}(\text{C}_2\text{H}_3\text{O}_2)_2$, colorless or white crystals very soluble in water.

Water for Injection, USP is chemically designated H_2O .

The flexible plastic container is fabricated from a specially formulated polyvinyl chloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient 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. Exposure to temperatures above $25^\circ\text{C}/77^\circ\text{F}$ 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.

CLINICAL PHARMACOLOGY

When administered intravenously, Normosol-M and 5% Dextrose Injection provides water and electrolytes (with dextrose as a readily available source of carbohydrate) for maintenance of daily fluid and electrolyte requirements, plus minimal carbohydrate calories. The electrolyte composition approaches that of the principal ions of normal plasma (extracellular fluid). The electrolyte concentration is hypotonic (112 mOsmol/liter) in relation to the extracellular fluid (280 mOsmol/liter). One liter provides approximately one-third of the average adult daily requirement for water and principal electrolytes in balanced proportions, with acetate as a bicarbonate alternate, plus 170 calories from dextrose.

Solutions containing carbohydrate in the form of dextrose restore blood glucose levels

and supply calories. Carbohydrate in the form of dextrose may aid in minimizing liver glycogen depletion and exerts a protein-sparing action. Dextrose injected parenterally undergoes oxidation to carbon dioxide in water.

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. Sodium (Na^+) is the principal cation of the extracellular fluid and plays a large part in the therapy of fluid and electrolyte disturbances. Chloride (Cl^-) has an integral role in buffering action when oxygen and carbon dioxide exchange occurs in the red blood cells. The distribution and excretion of sodium (Na^+) and chloride (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output.

Potassium acetate in water dissociates to provide potassium (K^+) and acetate (CH_3COO^-) ions. Potassium is the chief cation of body cells (160 mEq/liter of intracellular water). It is found in low concentration in plasma and extracellular fluids (3.5 to 5.0 mEq/liter) in a healthy adult and child over 10 days old; 3.5 to 6.0 mEq/liter in a child less than 10 days old. Potassium plays an important role in electrolyte balance. Normally about 80 to 90% of the potassium intake is excreted in the urine; the remainder in the stools and to a small extent, in the perspiration. The kidney does not conserve potassium well so that during fasting or in patients on a potassium-free diet, potassium loss from the body continues resulting in potassium depletion.

Magnesium acetate in water dissociates to provide magnesium (Mg^{++}) and acetate (CH_3COO^-) ions. Magnesium is the second most plentiful cation of the intracellular fluids. It is an important cofactor for enzymatic reactions and plays an important role in neurochemical transmission and muscular excitability. Normal plasma concentration ranges from 1.5 to 2.5 or 3.0 mEq per liter. Magnesium is excreted solely by the kidney at a rate proportional to the plasma concentration and glomerular filtration.

Acetate anion (CH_3COO^-), a source of hydrogen ion acceptors, serves as an alternate source of bicarbonate (HCO_3^-) by metabolic conversion in the liver. This has been shown to proceed readily even in the presence of severe liver disease. Thus, acetate anion exerts a mild systemic antiacidotic action that may be advantageous during fluid and electrolyte replacement therapy.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production). Average normal pediatric daily requirements are based on the child's weight as described in the table below:

Weight	Fluid Requirements
Up to 10 kg	100 mL/kg
11 to 20 kg	1,000 mL + 50 mL/kg for each kg above 10 kg
Above 20 kg	1,500 mL + 20 mL/kg for each kg above 20 kg

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE

Normosol-M and 5% Dextrose Injection (Multiple Electrolytes and 5% Dextrose Injection Type 1, USP) is indicated for parenteral maintenance of routine daily fluid and electrolyte requirements with minimal carbohydrate calories from dextrose. Magnesium in the formula may help to prevent iatrogenic magnesium deficiency in patients receiving prolonged parenteral therapy.

CONTRAINDICATIONS

None known.

WARNINGS

Solutions containing sodium ions 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.

Solutions which contain potassium 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.

In patients with diminished renal function, administration of solutions containing sodium or potassium ions may result in sodium or potassium retention.

Solutions containing acetate should be used with great care in patients with metabolic or respiratory alkalosis, and in those conditions in which there is an increased level or an impaired utilization of acetate, such as severe hepatic insufficiency.

Administration of this solution 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 administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

PRECAUTIONS

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.

Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions, to patients receiving corticosteroids or corticotropin.

Solutions containing acetate should be used with caution, as excess administration may result in metabolic alkalosis.

Solutions containing dextrose should be used with caution in patients with known subclinical or overt diabetes mellitus.

Do not administer unless solution is clear and container is undamaged. Discard unused

portion.

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

Pregnancy Category C.

Animal reproduction studies have not been conducted with Normosol-M and 5% Dextrose Injection. It is also not known whether this solution can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This solution should be given to a pregnant woman only if clearly needed.

Pediatric Use.

The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates and very small infants the volume of fluid may affect fluid and electrolyte balance.

Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

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.

OVERDOSAGE

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See **WARNINGS**, **PRECAUTIONS** and **ADVERSE REACTIONS**.

DOSAGE AND ADMINISTRATION

Normosol-M and 5% Dextrose Injection is administered by intravenous infusion. The dose is dependent upon the age, weight and clinical condition of the patient. A daily total amount of 1500 mL/M² of body surface will meet the usual adult daily requirements for water and principal electrolytes in patients unable to take anything by mouth. The usual daily maintenance amount for an average adult (70 kg and 1.8 square meters of body surface) is approximately three liters.

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 birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Drug Interactions

Additives may be incompatible. Consult with pharmacist, if available. When introducing

additives, use aseptic technique, mix thoroughly and do not store.

To avoid precipitation of calcium salts that may occur when certain drugs are added, Normosol-M and 5% Dextrose Injection does not contain calcium.

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

INSTRUCTIONS FOR USE

To Open

Tear outer wrap at notch and remove solution container. 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.

If supplemental medication is desired, follow directions below before preparing for administration.

To Add Medication

1. Prepare additive port.
2. Using aseptic technique and an additive delivery needle of appropriate length, puncture resealable additive port at target area, inner diaphragm and inject. Withdraw needle after injecting medication.
3. The additive port may be protected by covering with an additive cap.
4. Mix container contents thoroughly.

To Administer

1. Attach administration set per manufacturer's instructions.
2. Regulate rate of administration per institutional policy.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

Normosol-M and 5% Dextrose Injection (Multiple Electrolytes and 5% Dextrose Injection Type 1, USP) is supplied in single-dose flexible plastic containers.

NDC No.	Product	Container Size (mL)
0409-7965-03	Normosol-M and 5% Dextrose Injection (Multiple Electrolytes and 5% Dextrose Inj., Type 1, USP)	500
0990-7965-03	Normosol-M and 5% Dextrose Injection (Multiple Electrolytes and 5% Dextrose Inj., Type 1, USP)	500
0409-7965-09	Normosol-M and 5% Dextrose Injection (Multiple Electrolytes and 5% Dextrose Inj., Type 1, USP)	1000
0990-7965-09	Normosol-M and 5% Dextrose Injection (Multiple Electrolytes and 5% Dextrose Inj., Type 1, USP)	1000

ICU Medical is transitioning NDC codes from the "0409" to a "0990" labeler code. Both NDC codes are expected to be in the market for a period of time.

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Revised: March, 2020

IFU0000171

ICU Medical, Inc., Lake Forest, Illinois, 60045, USA

PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label

1000 mL

NDC 0990-7965-09

**NORMOSOL®-M AND
5% DEXTROSE INJECTION**

**MULTIPLE ELECTROLYTES AND
5% DEXTROSE INJECTION TYPE 1, USP**

EACH 100 mL CONTAINS DEXTROSE, HYDROUS 5 g; SODIUM CHLORIDE 234 mg; POTASSIUM ACETATE 128 mg; MAGNESIUM ACETATE, ANHYDROUS 21 mg IN WATER FOR INJECTION. MAY CONTAIN HYDROCHLORIC ACID FOR pH ADJUSTMENT. ELECTROLYTES PER 1000 mL (NOT INCLUDING pH ADJUSTMENT); SODIUM 40 mEq; POTASSIUM 13 mEq; MAGNESIUM 3 mEq; CHLORIDE 40 mEq; ACETATE 16 mEq. 363 mOsmol/LITER (CALC). pH 5.0 (4.0 to 6.5)

ADDITIVES MAY BE INCOMPATIBLE. CONSULT WITH PHARMACIST, IF AVAILABLE. WHEN INTRODUCING ADDITIVES, USE ASEPTIC TECHNIQUE, MIX THOROUGHLY AND DO NOT STORE.

SINGLE-DOSE CONTAINER. USUAL DOSAGE: SEE INSERT. FOR I.V. USE. STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

RX ONLY

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CONTAINS DEHP

IMP0000054
ICU Medical, Inc.,
Lake Forest, Illinois, 60045, USA
icumedical

1000 mL



NDC 0990-7965-09

NORMOSOL[®]-M AND 5% DEXTROSE INJECTION

***MULTIPLE ELECTROLYTES AND
5% DEXTROSE INJECTION TYPE 1, USP***

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Rx ONLY

CONTAINS DEHP

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ICU Medical, Inc.,
Lake Forest, Illinois, 60045, USA



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dextrose monohydrate, sodium chloride, potassium acetate, and magnesium acetate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0990-7965
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R00K)	DEXTROSE MONOHYDRATE	5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	234 mg in 100 mL
POTASSIUM ACETATE (UNII: M911911U02) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM ACETATE	128 mg in 100 mL
MAGNESIUM ACETATE (UNII: 0E95JZY48K) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM ACETATE	21 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0990-7965-09	12 in 1 CASE	02/08/2021	
1		1 in 1 POUCH		
1		1000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017610	02/08/2021	

Labeler - ICU Medical Inc. (118380146)