HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use GLYCOPHOS safely and effectively. See full prescribing information for GLYCOPHOS.

GLYCOPHOS® (sodium glycerophosphate injection), for intravenous use
Initial U.S. Approval: 2026

INDICATIONS AND USAGE

Glycophos is a phosphorus replacement product indicated as a source of phosphorus in adults and pediatric patients 12 years and older as part of parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated. (1)

DOSAGE AND ADMINISTRATION

Important Administration Information
- Glycophos is not for direct intravenous infusion. Glycophos must be diluted and used as a PN admixture. (2.1)
- Check serum phosphorus and calcium concentrations and normalize calcium concentration prior to administration. (2.1)

Important Preparation Instructions
- Calcium and phosphate ratios must be considered. Excess addition of calcium and phosphate, especially in the form of mineral salts, may result in the formation of calcium-phosphate precipitates. (2.2)
- The sodium amount is 2 mEq/mL (46 mg/mL) and should be factored into the total sodium dose calculation for the prepared PN admixture. (2.2)
- See full prescribing information for instructions on preparation and administration. (2.1, 2.2)

Recommended Dosage
- Glycophos provides phosphorus 1 mmol/mL (sodium 2 mEq/mL). (2.3)
- The recommended dosage for Glycophos in adults and pediatric patients 12 years and older is 20 to 40 mmol/day when used in PN admixture. (2.3)

DOSAGE FORMS AND STRENGTHS

Injection:
- Phosphorus 20 mmol/20 mL (1 mmol/mL) and sodium 40 mEq/20 mL (2 mEq/mL) in a single-dose vial. (3)
- Phosphorus 100 mmol/100 mL (1 mmol/mL) and sodium 200 mEq/100 mL (2 mEq/mL) in a Pharmacy Bulk Package vial. (3)

CONTRAINDICATIONS

- Hyperphosphatemia (4)
- Hypernatremia (4)
- Hypercalcemia or hypocalcemia (4)
- eGFR less than 30 mL/min/1.73 m^2 and patients receiving dialysis treatment (4)
- history of a hypersensitivity reaction to sodium glycerophosphate or any of the inactive ingredients (4)

WARNINGS AND PRECAUTIONS

- Pulmonary Embolism due to Pulmonary Vascular Precipitates: If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation. (5.1)
- Hyperphosphatemia and Hypocalcemia: Monitor serum phosphorus and calcium concentrations during and following infusion. (5.2)
- Risk of Sodium Retention: Closely monitor patients with congestive heart failure, renal impairment, cirrhosis, and other conditions with risk for edema and/or sodium retention. Consider all sources of sodium, including concomitant use of sodium-retaining drugs, and adjust dose as needed. (5.3)
- Hypersensitivity Reactions: Monitor for signs or symptoms and discontinue infusion if reactions occur. (5.4)
- Aluminum Toxicity: Increased risk in patients with renal impairment, including preterm infants. (5.5, 8.4)
- Hypomagnesemia: Reported in patients with hypercalcemia and diabetic ketoacidosis. Monitor serum magnesium concentrations during treatment. (5.6)
- Vein Damage and Thrombosis: Infuse concentrated or hyperosmolar solutions through a central catheter. (5.7)

ADVERSE REACTIONS

Common adverse reactions include hyperphosphatemia, hypocalcemia, hypernatremia, and hypomagnesemia. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 7/2026

FRESENIUS KABI

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Glycophos®

(sodium glycerophosphate injection) Rx only

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Glycophos is indicated as a source of phosphorus in adults and pediatric patients 12 years and older as part of parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Information

- Glycophos is not for direct intravenous infusion. Prior to administration, Glycophos must be diluted and used as a PN admixture.
- Visually inspect the PN admixture for particulate matter and discoloration before and after dilution and prior to administration.
- Administer the PN admixture containing Glycophos via intravenous infusion into a central or peripheral vein. The choice of a peripheral or central venous route should depend on the osmolarity of the final infusate. Infuse PN admixtures with osmolarity of 900 mOsmol/L or greater through a central catheter *[see Warnings and Precautions (5.7)]*.
- Check serum phosphorus and calcium concentrations prior to administration of Glycophos. Normalize calcium concentration before administering Glycophos *[see Contraindications (4), Warnings and Precautions (5.2)]*.
- Complete the intravenous infusion of PN admixture with Glycophos within 24 hours after removal from refrigeration. Discard any remaining admixture.

2.2 Important Preparation Information

- Add Glycophos to the PN admixture in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area). Use aseptic technique to avoid inadvertent contamination during mixing of solutions and addition of other nutrients.
- Add Glycophos and other nutrients to the PN admixture in the following suggested order:
  1) Amino acids and dextrose
  2) Glycophos
  3) Other electrolytes, including calcium
  4) Lipids, if included.
- Prepare admixture in accordance with healthcare institution's policies and procedures and following automated compounder instructions, as indicated.
- Discard unused portion of the single-dose vial (20 mL).
- For Pharmacy Bulk Package Vial (100 mL),
  - Penetrate vial closure only one time with a suitable sterile transfer device or dispensing set that allows for measured dispensing of the contents.
  - Use Glycophos promptly (within 4 hours at room temperature 20°C to 25°C (68°F to 77°F)) after the container closure has been penetrated. Discard any unused portion.
- Because additives may be incompatible, evaluate all additions to the PN admixture for compatibility and stability of the resulting PN admixture. Questions about compatibility may be directed to Fresenius Kabi USA.
- Calcium and phosphate ratios must be considered. Excess addition of calcium and phosphate, especially in the form of mineral salts, may result in the formation of calcium-phosphate precipitates *[see Warnings and Precautions (5.1)]*. Calcium-phosphate stability in PN admixtures is dependent on the pH of the admixture, temperature, and relative concentration of each ion.
- The sodium amount of Glycophos is 2 mEq/mL (46 mg/mL) and should be factored into the total sodium dose calculation for the prepared PN admixture *[see Warnings and Precautions (5.3)]*.
- Inspect the final PN admixture containing Glycophos to ensure that:
  - precipitates have not formed during mixing or addition of additives and inspect again before administration.
  - emulsion has not separated, if lipids have been added. Separation of the emulsion can be visibly identified by a yellowish streaking or the accumulation of yellowish droplets in the admixed emulsion.
  - Discard the PN admixture if any precipitates are observed or emulsion has separated.
- Administer PN admixtures containing Glycophos promptly after mixing. If the PN admixture is not used promptly, do not store longer than 4 hours at room temperature 20°C to 25°C (68°F to 77°F) or refrigerate the PN admixture at 2°C to 8°C (36°F to 46°F) for up to 24 hours.
- Protect the PN admixture containing Glycophos from light.

2.3 Recommended Dosage

- Glycophos provides phosphorus at 1 mmol/mL.
- The recommended daily dosage of Glycophos in adults and pediatric patients 12 years and older is 20 to 40 mmol/day, administered via intravenous infusion as a PN admixture.
- The recommended Glycophos daily dosage as part of the PN admixture is dependent on the individual needs of the patient and the amount of phosphorus from other sources. The rate of administration may be dependent on the patient's individual clinical condition.
- In patients with an eGFR greater than or equal to 30 mL/min/1.73 m^2 to less than 60 mL/min/1.73 m^2, start at the low end of the dosage range.

3 DOSAGE FORMS AND STRENGTHS

Injection: Sterile, non-pyrogenic, clear, colorless to slightly yellowish solution containing:
- Phosphorus 20 mmol/20 mL (1 mmol/mL) and sodium 40 mEq/20 mL (2 mEq/mL) in a single-dose vial.
- Phosphorus 100 mmol/100 mL (1 mmol/mL) and sodium 200 mEq/ 100 mL (2 mEq/mL) in a Pharmacy Bulk Package vial.

4 CONTRAINDICATIONS

Glycophos is contraindicated in patients with:
- Hyperphosphatemia *[see Warnings and Precautions (5.2)]*.
- Hypernatremia *[see Warnings and Precautions (5.3)]*.
- Hypercalcemia or hypocalcemia *[see Warnings and Precautions (5.2)]*.
- eGFR less than 30 mL/min/1.73 m^2 or patients receiving dialysis treatment *[see Warnings and Precautions (5.2, 5.3)]*.
- History of a hypersensitivity reaction to sodium glycerophosphate or any of the inactive ingredients. Reactions have included anaphylaxis *[see Warnings and Precautions (5.4)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Pulmonary Embolism Due to Pulmonary Vascular Precipitates

Pulmonary vascular emboli and pulmonary distress related to precipitates in the pulmonary vasculature have been described in patients receiving admixed products containing calcium and phosphate or PN. The cause of precipitate formation has not been determined in all cases; however, in some fatal cases, pulmonary emboli occurred as a result of calcium phosphate precipitates. Precipitation following passage through an in-line filter and suspected in vivo precipitate formation have also been reported.

If signs of pulmonary distress occur, stop the PN infusion and initiate a medical evaluation. Visually inspect the prepared solution *[see Dosage and Administration (2.2, 2.3)]*, the infusion set, and catheter prior to administration as well as periodically during the administration.

5.2 Hyperphosphatemia and Hypocalcemia

Hyperphosphatemia can occur with intravenous administration of phosphate-containing solutions, especially in patients with renal impairment. Hyperphosphatemia can cause the formation of insoluble calcium phosphorus products with consequent hypocalcemia, neurological irritability with tetany, nephrocalcinosis with acute kidney injury and, more rarely, cardiac irritability with arrhythmias.

Obtain serum phosphorus and calcium concentrations prior to administration of Glycophos and normalize calcium before administering Glycophos *[see Dosage and Administration (2.1)]*. Glycophos is contraindicated in patients with hyperphosphatemia and/or hypocalcemia *[see Contraindications (4)]*.

Glycophos containing PN admixtures should be infused slowly to avoid phosphorus intoxication and hypocalcemia *[see Dosage and Administration (2.3)]*.

Monitor serum phosphorus and calcium concentrations during treatment with Glycophos.

5.3 Risk of Sodium Retention

Closely monitor patients with congestive heart failure, renal impairment, cirrhosis, and in other clinical states in which there exists edema and/or sodium retention during Glycophos use *[see Use in Specific Populations (8.6)]*. The sodium content of Glycophos is 2 mEq/mL (46 mg/mL) and should be factored into the total sodium dose calculation for the prepared PN admixture.

Concomitant use of Glycophos with sodium-retaining drugs (e.g., corticosteroids, corticotropin, non-steroidal anti-inflammatory agents) may lead to edema due to fluid retention. Patients should be monitored for swelling and weight gain. If edema occurs, consider dose adjustment or discontinuation of the sodium-retaining drug *[see Drug Interactions (7.1)]*.

5.4 Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, have been reported with Glycophos *[see Adverse Reactions (6)]*. Glycophos is contraindicated in patients with a history of a hypersensitivity reaction to sodium glycerophosphate or any of the active or inactive ingredients *[see Contraindications (4)]*. Stop administration of the PN admixture containing Glycophos immediately if signs or symptoms of a hypersensitivity reaction develop. Initiate appropriate treatment as clinically indicated.

5.5 Aluminum Toxicity

Glycophos contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Preterm 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 preterm 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.

Glycophos is not approved for use in pediatric patients less than 12 years of age, including preterm infants. Exposure to aluminum from Glycophos when administered at the maximum recommended dosage is not more than 0.5 mcg/kg/day *[see Dosage and Administration (2.3), Description (11)]*.

When prescribing Glycophos for use in PN solutions containing other small volume parenteral products, limit the total daily patient exposure to aluminum in the PN admixture to no more than 5 mcg/kg/day *[see Use in Specific Populations (8.4)]*.

5.6 Hypomagnesemia

Intravenous infusion of phosphate has been reported to cause a decrease in serum magnesium (and calcium) concentrations when administered to patients with hypercalcemia or diabetic ketoacidosis. Monitor serum magnesium concentrations during Glycophos treatment.

5.7 Vein Damage and Thrombosis

Glycophos must be diluted and administered via intravenous infusion as an PN admixture. Do not infuse directly intravenously without dilution. The infusion of hyperosmolar solutions into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis. The primary complication of peripheral administration is venous thrombophlebitis, which manifests as pain, erythema, tenderness or a palpable cord. If thrombophlebitis develops, remove the catheter as soon as possible and initiate appropriate medical

treatment.PN admixtures containing Glycophos with an osmolarity of 900 mOsmol/L or greater must be infused through a central catheter *[see Dosage and Administration (2.1)]*.

5.8 Laboratory Monitoring

Monitor serum phosphorus, sodium, calcium, and magnesium concentrations during treatment *[see Dosage and Administration (2.1, 2.2, 2.3)]*.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Pulmonary Embolism Due to Pulmonary Vascular Precipitates *[see Warnings and Precautions (5.1)]*.
- Hyperphosphatemia and Hypocalcemia *[see Warnings and Precautions (5.2)]*.
- Risk of Sodium Retention *[see Warnings and Precautions (5.3)]*.
- Hypersensitivity Reactions *[see Warnings and Precautions (5.4)]*.
- Aluminum Toxicity *[see Warnings and Precautions (5.5)]*.
- Hypomagnesemia *[see Warnings and Precautions (5.6)]*.
- Vein Damage and Thrombosis *[see Warnings and Precautions (5.7)]*.

The following adverse reactions associated with use of intravenous Glycophos (Table 1) were identified in clinical studies or postmarketing reports. Given that some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to product exposure.

TABLE 1: Adverse Reactions Reported in Clinical Studies or Postmarketing Reports with Intravenous Glycophos

System Organ Class	Adverse Reactions
Metabolism and Nutrition Disorders	Hyperphosphatemia Hypocalcemia Hypernatremia
Cardiac Disorders	Hypotension, Arrhythmia, Heart block Cardiac arrest, Bradycardia, Chest pain, ECG changes
Vascular Disorders	Phlebitis
Respiratory, Thoracic, and Mediastinal Disorders	Dyspnea
Renal and Urinary Disorders	Acute phosphate nephropathy (i.e., nephrocalcinosis with acute kidney injury) Decreased urine output Chronic kidney disease
Gastrointestinal Disorders	Diarrhea, stomach pain
Musculoskeletal and Connective Tissue Disorders	Weakness
Nervous System Disorders	Confusion, lethargy, paralysis, paresthesia
Skin and Subcutaneous Tissue Disorders	Pruritus Rash
Immune System Disorders	Anaphylaxis

7 DRUG INTERACTIONS

7.1 Drugs with Effects on Sodium Retention

Concomitant use of Glycophos with sodium-retaining drugs (e.g., corticosteroids, corticotropin or non-steroidal anti-inflammatory agents) may lead to edema due to fluid retention. Monitor patients for swelling and weight gain. If edema occurs, consider modifying the Glycophos dosage or discontinue the concomitant sodium-retaining drug *[see Warnings and Precautions (5.3)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Administration of the recommended dosage of Glycophos is not expected to cause major birth defects, miscarriage, or adverse maternal or fetal outcomes. Phosphorus is an essential mineral element. Parenteral supplementation with Glycophos, as part of PN, should be considered if a pregnant woman's requirements cannot be fulfilled by oral or enteral intake. Animal reproduction studies have not been conducted with intravenous sodium glycerophosphate.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

8.2 Lactation

Risk Summary

Phosphate and glycerol are present in human milk. Administration of the recommended dosage of Glycophos is not expected to cause harm to a breastfed infant. There is no information on the effects of Glycophos on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Glycophos and any potential adverse effects on the breastfed child from Glycophos or from underlying maternal conditions.

8.4 Pediatric Use

The safety and effectiveness of Glycophos have been established in pediatric patients 12 years and older as a source of phosphorus as part of parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated. Use of Glycophos for this indication is supported by established safety and effectiveness of an inorganic phosphate product in adults with supportive pharmacokinetic data of Glycophos in adults *[see Clinical Pharmacology (12.3)]*. Glycerophosphate is hydrolyzed by serum alkaline phosphatase (ALP) to glycerol and phosphate, and the activity of ALP is expected to be similar in patients 12 years of age and older.

Glycophos contains aluminum that may be associated with central nervous system and bone toxicity *[see Warnings and Precautions (5.5)]*.

Glycophos contains glycerophosphate which is hydrolyzed by ALP in plasma to phosphate and glycerol. Glycerol may increase plasma osmolarity. When prescribing Glycophos, consider the combined daily amount of glycerol from all sources (e.g., intravenous lipid emulsions) including Glycophos, which may increase glycerol exposure and lead to an increased risk of systemic toxicity.

The safety and effectiveness of Glycophos have not been established in pediatric patients younger than 12 years old. Use of Glycophos in this age group may result in increased plasma levels of glycerol.

8.5 Geriatric Use

It is not known whether geriatric patients treated with Glycophos respond differently from younger adult patients. In general, dose selection for an elderly patient should be cautious, starting at the low end of the dosing range because of the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant diseases or other drug therapy. Monitor renal function during treatment *[see Use in Specific Populations (8.6)]*.

8.6 Renal Impairment

Phosphorus is known to be substantially excreted by the kidney and the risk of adverse reactions to Glycophos may be greater in patients with renal impairment. In patients with renal impairment, administration of solutions containing sodium ions, including Glycophos, may result in sodium retention *[see Warnings and Precautions (5.2, 5.3)]*.

Glycophos is contraindicated in patients with eGFR less than 30 mL/min/1.73 m^2 *[see Contraindications (4)]*.

In patients with eGFR greater than or equal to 30 mL/min/1.73 m^2 to less than 60 mL/min/1.73 m^2, start at the low end of the dosage range and monitor serum phosphorus, sodium, calcium, and magnesium levels *[see Dosage and Administration (2.3)]*.

10 OVERDOSAGE

Serious adverse reactions may occur from Glycophos overdosage *[see Warnings and Precautions (5.2, 5.3, 5.4, 5.5, 5.6)]*.

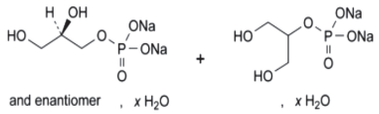
Hyperphosphatemia is particularly a risk in patients with renal failure. Hyperphosphatemia can lead to hypocalcemia, which may be severe and result in ectopic calcification, particularly in patients with initial hypercalcemia. Tissue calcification may cause hypotension and organ damage and result in acute renal failure.

In the event of overdosage, discontinue Glycophos infusion immediately and institute general supportive measures, including electrocardiogram monitoring, laboratory monitoring, and correction of serum electrolyte concentrations, especially phosphorus, calcium, sodium, and magnesium.

11 DESCRIPTION

Glycophos is a phosphorus replacement product containing hydrated sodium glycerophosphate

Sodium glycerophosphate is chemically designated as given below, with a molecular weight of 216.04 g/mol and is freely soluble in water.



Glycophos (sodium glycerophosphate injection), for intravenous use after dilution, is supplied as a clear, colorless to slightly yellowish, sterile, non-pyrogenic concentrated solution in 20 mL single-dose vials or 100 mL Pharmacy Bulk Package vials. Each mL contains 216 mg of anhydrous sodium glycerophosphate (corresponding to sodium glycerophosphate pentahydrate 306 mg and equivalent to phosphorus 31 mg [1 mmol]), sodium 46 mg (2 mEq), and Water for Injection.

Hydrochloric acid and/or sodium hydroxide may be added for pH adjustment (pH 7.2-7.6). The osmolarity is 2.8 mOsmol/mL (calc).

Glycophos contains no more than 250 mcg/L of aluminum *[see Warnings and Precautions (5.5)]*.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Sodium glycerophosphate, an organic phosphate salt, functions as a source of phosphorus. Phosphorus in the form of organic and inorganic phosphate has a variety of biochemical functions in all organs and tissues, including critical roles in nucleic acid structure, energy storage and transfer, cell signaling, cell membrane composition and structure, acid-base balance, mineral homeostasis, and bone mineralization.

12.2 Pharmacodynamics

The exposure-response relationship and time course of pharmacodynamic response for the safety and effectiveness of sodium glycerophosphate have not been fully characterized.

12.3 Pharmacokinetics

In a clinical pharmacology study conducted in healthy adult subjects that compared pharmacokinetics of phosphate following a single intravenous infusion of Glycophos in comparison to inorganic phosphate given at the same dose (80 mmol phosphorus) via the same route of administration, serum phosphate concentration was slightly lower with Glycophos than inorganic phosphate, but the difference is not clinically meaningful for parenteral nutrition use.

Distribution

Approximately 85% of serum phosphate is free and ultra-filterable and 15% is protein-bound.

Elimination

Metabolism

Following intravenous administration, glycerophosphate is hydrolyzed in plasma to phosphate and glycerol by serum alkaline phosphatase.

Excretion

Intravenously infused phosphate not taken up by the tissues is excreted almost entirely in the urine.

Serum phosphorus is filterable by the renal glomeruli, and the greater than 80% of the filtered phosphorus is actively reabsorbed by the tubules.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Carcinogenicity studies have not been conducted with sodium glycerophosphate or other glycerophosphate salts.

Mutagenesis

Sodium glycerophosphate was negative in the bacterial reverse mutation (Ames) assay, the thymidine kinase gene mutation assay with mouse lymphoma L5178Y $TK^{+/-}$ cells, and the in vivo mouse micronucleus assay.

Impairment of Fertility

Fertility studies have not been conducted with sodium glycerophosphate or other glycerophosphate salts.

16 HOW SUPPLIED/STORAGE AND HANDLING

Glycophos (sodium glycerophosphate injection) is a clear and colorless to slightly yellowish solution supplied as:

Product Code	Unit of Sale	Strength (Concentration)	Packaging Type
344020	NDC 65219-346-20 Tray containing 25 units	Phosphorus 20 mmol/20 mL (1 mmol/mL) and Sodium 40 mEq/20 mL (2 mEq/mL)	NDC 65219-346-01 20 mL Single-Dose, plastic vial
344100	NDC 65219-348-10 Tray containing 20 units	Phosphorus 100 mmol/100 mL (1 mmol/mL) and Sodium 200 mEq/100 mL (2 mEq/mL)	NDC 65219-348-01 100 mL Pharmacy Bulk Package, plastic vial

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

Pharmacy Bulk Package vial: Use within 4 hours after initial container closure penetration when stored at room temperature 20°C to 25°C (68°F to 77°F) *[see Dosage and Administration (2.2)]*.

Store the PN admixture containing Glycophos under refrigeration at 2°C to 8°C (36°F to 46°F), for no longer than 24 hours *[see Dosage and Administration (2.2)]*.

The container closure is not made with natural rubber latex.

17 PATIENT COUNSELING INFORMATION

Inform patients, caregivers or home healthcare providers of the following:

- Glycophos may lead to pulmonary vascular precipitates and potentially fatal pulmonary emboli *[see Warnings and Precautions (5.1)]*.
- Hyperphosphatemia can occur with Glycophos treatment, especially in patients with renal impairment, which can result in hypocalcemia *[see Warnings and Precautions (5.2)]*.
- Glycophos may result in sodium retention in patients with diminished renal function *[see Warnings and Precautions (5.3)]*.
- Hypersensitivity reactions, including anaphylaxis, have been reported with Glycophos *[see Warnings and Precautions (5.4)]*.
- Glycophos contains aluminum and prolonged PN administration in patients with renal impairment may result in aluminum reaching toxic levels that are associated with central nervous system and bone toxicity *[see Warnings and Precautions (5.5)]*.
- Glycophos may cause hypomagnesemia when administered to patients with hypercalcemia or diabetic ketoacidosis *[see Warnings and Precautions (5.6)]*.
- Infusion of hyperosmolar solutions into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis *[see Warnings and Precautions (5.7)]*.

Manufactured by:

FRESENIUS KABI

Lake Zurich, IL 60047

www.fresenius-kabi.com/us

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