IMPORTANT PRESCRIBING INFORMATION

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FRESENIUS KABI

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

October 30, 2017

Subject: Temporary importation of Glycophos to address drug shortage issues

Dear Healthcare Professional,

Due to the critical shortage of phosphate injection in the U.S. market, Fresenius Kabi USA, LLC (Fresenius Kabi USA) is coordinating with the U.S. Food and Drug Administration (FDA) to provide an alternative treatment option during this critical shortage period. Fresenius Kabi USA has initiated temporary importation of a Glycophos™ 20 mL Injection Single Dose Plastic Vial into the U.S. market. This product is marketed in Europe, and is manufactured in the Fresenius Kabi Norway plant.

At this time, no other entity except Fresenius Kabi USA is authorized by the FDA to import or distribute Glycophos™ 20 mL Injection Single Dose Plastic Vial in the U.S. FDA has not approved Fresenius Kabi's Glycophos in the United States.

Effective immediately, and during this temporary period, Fresenius Kabi USA will offer the following presentation of phosphate injection:

Glycophos 20 mL Sterile Concentrate Single Dose Plastic Vial	
Chemical Name	Sodium Glycerophosphate
Phosphate Concentration	1 mMol per mL.
Type of Phosphate	Organic
Sodium	2 mEq per mL.
Fill Volume	20 mL.
Description	Single Dose Plastic Vial
Manufacturer	Fresenius Kabi Norge A/S

The vial and carton labels will display the text used when marketing the product in English speaking countries.

It is important to note that there are some key differences in the formulation and labeling between the current U.S. marketed phosphate injection products and Glycophos that you need to be aware of:

- **Glycophos** is an ***ORGANIC*** phosphate which is a different type of phosphate than the ***INORGANIC*** phosphate injection products currently marketed in the U.S.
- **Glycophos** contains 1 mMol of phosphate per 1 mL. of solution as compared to the phosphates currently marketed in the U.S. which contain 3 mMol of phosphate per 1 mL.
- The aluminum content of **Glycophos** is not more than 550 mcg/L.
- **Glycophos** does **NOT** contain a preservative and is intended for **single use**.
  - **Strict aseptic technique must always be maintained.**
  - **Glycophos is for administration to a single patient and is NOT intended for multiple use.**
- **Glycophos must be diluted before administration.**
- **Glycophos** is contraindicated in patients in a state of dehydration or with hypernatremia, hyperphosphatemia, severe renal insufficiency or shock.
- Any barcodes on **Glycophos** product will not be appropriately recognized by scanning systems used in the United States and should NOT be used. Institutions should manually input the product into their systems to confirm that barcode systems do not provide incorrect information when the product is scanned.
  - Alternative procedures should be followed to assure that the correct drug product is being prepared and administered to individual patients.
- The container closure is not made from natural rubber latex.
- The attached product comparison table highlights the key differences in strength, formulation and labeling between phosphate injection products currently available in the U.S. and **Glycophos**.

Refer to the Glycophos package insert for full prescribing information

This communication and product information is available on the Fresenius Kabi USA web site http://products.fresenius-kabi.us/product-323.html as well as on the FDA Drug Shortage web site. http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm.

To report adverse events or quality problems experienced with the use of this product, call Fresenius Kabi USA Vigilance or Medical Affairs at 1-800-551-7176, Monday – Friday, between the hours of 8 a.m. and 5 p.m. (CST), or e-mail adverse.events.USA@fresenius-kabi.com or productcomplaint.USA@fresenius-kabi.com.

Fresenius Kabi USA CONTACT NUMBERS: Please use the following contact numbers as appropriate:

Reason To Call	Department	Number
ADE Reporting	Vigilance Department	1-800-551-7176
Clinical/Technical Info. Or Product Complaint	Medical Affairs Department	
Product Availability & Ordering	Customer Service Department	1-888-386-1300

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/medwatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

Sincerely,

Melanie Power-Burns

Vice President, Quality and Compliance

Key Differences between U.S. Marketed Phosphate Injection Products and Glycophos

Current U.S. Marketed Inorganic Phosphate Injection, USP	Glycophos	What does this mean to you, as a Healthcare Professional?
Indications and contraindications: see package insert	Indications and contraindications: see package insert	Glycophos is indicated in adult patients and infants as a supplement in intravenous nutrition to meet the requirements of phosphate. Glycophos is contraindicated in patients in a state of dehydration or with hypernatremia, hyperphosphatemia, severe renal insufficiency or shock.
Sodium Phosphates and Potassium Phosphates contain 3 mMol of phosphate per mL.	Glycophos contains 1 mMol of phosphate per mL.	Glycophos contains 20 mLs in each plastic vial for a total concentration of 20 mMols of phosphate per vial. Glycophos must be diluted before administration.
Sodium Phosphates and Potassium Phosphates are **INORGANIC PHOSPHATE.**	Glycophos is an **ORGANIC PHOSPHATE.**	Organic phosphates tend to be more calcium compatible[1]. This means: • At higher concentrations, solutions of calcium and phosphate may exist together without precipitating into an insoluble salt complex. • In high pH solutions (admixtures above pH 6.0), organic phosphate is less likely to precipitate.
Barcode on container label	No unit of use barcode	Any barcodes on **Glycophos** product will not be appropriately recognized by scanning systems used in the United States and should NOT be used. Institutions should manually input the product into their systems and to confirm that barcode systems do not provide incorrect information when the product is scanned.
For questions regarding Glycophos in the United States, please contact Fresenius Kabi USA Medical Affairs at 1-800-551-7176 Option 4, Monday – Friday, between the hours of 8 a.m. and 5 p.m. (CST), or e-mail nutrition.medinfo.USA@fresenius-kabi.com.		

1. Data on file.

Comparison Table of U.S. Phosphate Injection Products to Glycophos

Product Name	Potassium Phosphates	Sodium Phosphates	Glycophos
Chemical Name	Potassium Phosphate	Sodium Phosphate	Sodium Glycerophosphate
Phosphate Concentration	3 mMol per mL	3 mMol per mL	1 mMol per mL
Type of Phosphate	Inorganic	Inorganic	Organic
Sodium	Does not contain	4 mEq per mL	2 mEq per mL
Potassium	4.4 mEq per mL	Does not contain	Does not contain
Fill Volume	5 mL, 15 mL, 50 mL	5 mL, 15 mL, 50 mL	20 mL
Description	Single Dose Vial	Single Dose Vial	Single Dose Plastic Vial
Companies	Fresenius Kabi USA, Pfizer	American Regent, Fresenius Kabi USA, Pfizer	Fresenius Kabi Norge A/S

Phosphate Label Product Comparison Table

	Potassium Phosphates (Inorganic)						Glycophos (Organic)
							
NDC#	00409-7295-01	63323-086-05	63323-086-15	63323-086-50			
Fill Volume	15 mL	5 mL	15 mL	50 mL			
Manufacturer	Pfizer	Fresenius Kabi USA	Fresenius Kabi USA	Fresenius Kabi USA			
Sodium Phosphates (Inorganic)							
							
NDC#	00409-7391-72	63323-170-05	63323-170-15	00517-3405-25	00517-3415-25	00517-3450-25	63323-241-20
Fill Volume	15 mL	5 mL	15 mL	5 mL	15 mL	50 mL	20 mL
Manufacturer	Pfizer	Fresenius Kabi USA	Fresenius Kabi USA	American Regent	American Regent	American Regent	Fresenius Kabi Norge A/S