**Fresenius Kabi USA, LLC**

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# PHOSPHATE INJECTION AVAILABILITY

May 29, 2013

Dear Healthcare Professional,

Due to the critical shortage of phosphate injection in the US market, Fresenius Kabi, USA LLC (Fresenius Kabi USA) is coordinating with the U.S. Food and Drug Administration (FDA) to provide and alternative treatment option during this critical shortage period.

At this time, FDA's regulatory discretion for the importation and distribution of Fresenius Kabi's Glycophos™ 20 mL Injection Single Dose Plastic Vial is limited to Fresenius Kabi USA during the critical shortage of phosphate injection. Importation or distribution of this product in the United States by any other entity is outside the scope of FDA's regulatory discretion, and FDA has not approved Fresenius Kabi's Glycophos™ product for marketing in the U.S.

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

| **Glycophos 20 mL<br>Sterile Concentrate<br>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 |

**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.
- **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 and 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 APP web site www.APPpharma.com 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 and Medical Affairs at 1-800-551-7176, Monday – Friday, between the hours of 8 a.m. and 5 p.m. (CST), or e-mail appmedicalinfo@APPpharma.com.

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

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

Adverse events may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail**: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- **Fax**: 1-800-FDA-0178

Sincerely,

Melanie Power-Burns
Senior Director, U.S. Quality & Compliance

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**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.<br><br>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.<br><br>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].<br>This means:<br>▪ At higher concentrations, solutions of calcium and phosphate may exist together without precipitating into an insoluble salt complex.<br><br>▪ In high pH solutions (admixtures above pH 6.0), organic phosphate is less likely to precipitate. |
| Information not available. | 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 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 Vigilance and Medical Affairs at 1-800-551-7176, Monday – Friday, between the hours of 8 a.m. and 5 p.m. (CST), or e-mail appmedicalinfo@APPpharma.com. | | |

1. Data on file.

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**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** | American Regent, Hospira | American Regent, Hospira | Fresenius Kabi Norge A/S |

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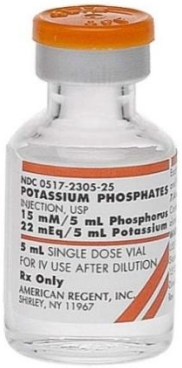
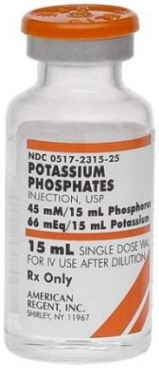
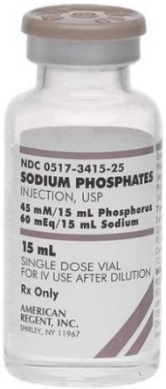
# Phosphate Label Product Comparison Table

| | Potassium Phosphates (Inorganic) | | | | Glycophos (Organic) |
|---|---|---|---|---|---|
| |  |  |  |  | |
| **NDC#** | 0409-7295-01 | 00517-2305-25 | 00517-2315-25 | 00517-2350-25 | |
| **Fill Volume** | 15 mL | 5 mL | 15 mL | 50 mL | |
| **Manufacturer** | Hospira | American Regent | American Regent | American Regent | |
| | **Sodium Phosphates (Inorganic)** | | | | |
| |  |  |  |  |  |
| **NDC#** | 00409-7391-72 | 00517-3405-25 | 00517-3415-25 | 00517-3450-25 | 63323-241-20 |
| **Fill Volume** | 15 mL | 5 mL | 15 mL | 50 mL | 20 mL |
| **Manufacturer** | Hospira | American Regent | American Regent | American Regent | Fresenius Kabi Norge A/S |