

Phosphate Injection Availability Frequently Asked Questions

Q. What is Glycophos™?

A. Glycophos is sodium glycerophosphate, which is an organic phosphate. It is indicated for adult and infant patients as a supplement in intravenous nutrition to meet phosphate requirements. Glycophos is manufactured in Norway by Fresenius Kabi Norge A/S.

Q. Why is Fresenius Kabi USA importing Glycophos™?

A. Due to the critical shortage of phosphate injection in the U.S. market, 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.

Q. How is Glycophos[™] different from current U.S. marketed phosphate products?

- **A.** It is important to note that there are 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 1mL as compared to the phosphates currently marketed in the U.S. which contain 3mMol of phosphate per mL.
 - Glycophos does **NOT** contain a preservative and is intended for **single use**.
 - Glycophos must be diluted before administration.
 - 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.

Please refer to a Dear Healthcare Professional letter for a complete list of clinical differences and the Glycophos package insert for full prescribing information at <u>www.fresenius-kabi.us</u>.

Q. What is the difference between organic and inorganic phosphate?

A. Organic phosphates tend to be more calcium compatible. 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.

Q. Is Glycophos[™] an FDA approved product?

A. No. Glycophos is not FDA approved in the U.S.

Q. What container is Glycophos[™] available in?

A. Glycophos is available in a 20mL **single dose** plastic vial made from polypropylene. The container closure is not made from natural rubber latex.

Q. How long will Glycophos[™] be available in the U.S.?

A. Glycophos[™] is being imported to assist in this time of shortage.

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

If you have questions regarding product availability, please contact Customer Service at 1-888-386-1300, Monday – Friday, between the hours of 7:00 a.m. and 6:00 p.m. (CST).