

## IMPORTANT DRUG INFORMATION ABOUT KEPIVANCE

October 2023  
Sobi Inc.  
77 4th Avenue, 3rd Floor  
Waltham, MA 02451  
USA



<b>Subject:       Kepivance® (palifermin) for injection, for intravenous use</b> <b>Clarification regarding the labeled quantity and change in vial size</b>
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Dear Health Care Provider:

The purpose of this letter is to inform you of a change in the size of the Kepivance® vial and to clarify the labeled content stated in the U.S. prescribing information, on the carton and on the vial. Please see the bullets below for a summary of the relevant changes and clarification regarding the drug quantity and concentration.

- The size of the vial has been changed from a 5 mL vial to a 6 mL vial
- The labeled content has been changed from the gross value of 6.25 mg/vial to the net value of 5.16 mg/vial to follow 21 CFR 201.51(g)
- There has been no change to the actual drug quantity contained within each vial or to the reconstitution procedures
- The concentration of the reconstituted drug product is still 5 mg/mL when the vial is reconstituted with 1.2 mL Sterile Water for Injection

### **Reporting Adverse Events**

Health care providers and patients are encouraged to report suspected adverse reactions in patients taking Kepivance to Sobi, Inc. at 1-866-773-5274.

Adverse events, medication errors or quality problems experienced with the use of this product may also 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](http://www.fda.gov/medwatch/report.htm)
- Regular mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://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).

## **IMPORTANT DRUG INFORMATION ABOUT KEPIVANCE**

You may also contact our medical information department at 1-866-773-5274 ([medinfo.us@sobi.com](mailto:medinfo.us@sobi.com)) if you have any questions about the information contained in this letter or the safe and effective use of Kepivance®.

This letter is not intended as a complete description of the benefits and risks related to the use of Kepivance®. Please refer to the enclosed full prescribing information.

Sincerely,

Matthew Wojdyla, PharmD  
Senior Medical Director, North America