



## **FRESENIUS USA MARKETING, INC. PHARMACEUTICAL RETURN POLICY**

Effective Date: July 28, 2016

### **I. Applicability of Return Policy**

This Pharmaceutical Return Policy (“Return Policy”) applies to Venofer<sup>®</sup>, Velphoro<sup>®</sup>, Phoslyra<sup>®</sup>, PhosLo<sup>®</sup>, and any other pharmaceutical products added by exhibit hereto, marketed and sold by Fresenius USA Marketing, Inc. (“FUSA”).

Any terms and conditions of this Return Policy that are specific to a particular product will be set forth in an exhibit for that product. In the event of a conflict between this Return Policy and any of its exhibits, the exhibit will prevail.

This Return Policy applies only to products purchased from FUSA by a wholesale distributor or directly from FUSA by a customer. Customers who purchase indirectly through a wholesale distributor must look to their distributors’ policies for the terms of any returns, credits, exchanges or replacements.

This Return Policy does not apply to products purchased from sources outside the United States and its territories.

### **II. Returnable Products**

FUSA may accept returns of the following products for credit, exchange or replacement, as applicable, provided that all terms and conditions below and elsewhere in this Return Policy are met.

#### **A. Authorized Products**

##### **1. Claims for Loss or Damage in Shipment**

- Claims for loss, shortage, breakage, leakage or other visible damage of or to products occurring in transit must be made to FUSA within forty-eight (48) hours of the date of receipt and noted to the carrier on the

receiving document. Damaged material should be left in original cartons for inspection.

- Claims for concealed loss or damage to products must be made to FUSA within five (5) days of the date of receipt. Concealed loss or damage must be inspected by the delivery carrier within such five (5) day period and carrier's report must be forwarded to FUSA prior to approval. FUSA reserves the right to have a local representative inspect the goods damaged in transit.
- The buyer's sole and exclusive remedy for authorized returns of products damaged in transit is replacement of such damaged products. No other remedy (including, but not limited to, incidental, consequential, or other damages of any kind) is available.

2. Claims for Defective

- Claims for products that are defective must be made to FUSA within forty-eight (48) hours of discovery, not to exceed five (5) business days from date of receipt.
- The buyer's sole and exclusive remedy for authorized returns of defective products is replacement of such defective products. No other remedy (including, but not limited to, incidental, consequential, or other damages of any kind) is available.

3. Claims for Incorrect Shipments

- Claims for products that are incorrectly shipped by FUSA or shipped in excess of the amount ordered must be made to FUSA within forty-eight (48) hours of discovery, not to exceed five (5) business days from date of receipt.
- Claims for incomplete product orders must be made to FUSA within forty-eight (48) hours of discovery, not to exceed five (5) business days from date of receipt of the partial order.
- The buyer's sole and exclusive remedy for authorized returns of products incorrectly shipped or products shipped in excess of the amount ordered is the no-cost return of such products for exchange or credit. The buyer's sole and exclusive remedy for incomplete orders is credit or replacement at FUSA's sole discretion. No other remedy (including, but not limited to, incidental, consequential, or other damages of any kind) is available.

4. Claims for Recalled Products

- Recalled products must be returned separately from other returned products, in accordance with the recall notice.

B. Expired Products

- FUSA may accept products for partial credit, at FUSA's sole discretion, to the extent the products are returned no earlier than three (3) months prior to the expiration date of the products and no later than six (6) months after the expiration date (the "Expiration Window"). Products expire on the last day of the month indicated on the packaging.
- The buyer will receive partial credit for authorized returns of products within the Expiration Window upon return of the product to FUSA or its designated agent. The buyer's sole and exclusive remedy for authorized returns of products within the Expiration Window is partial credit for such products. No other remedy (including, but not limited to, incidental, consequential, or other damages of any kind) is available.
- Seventy-five percent (75%) credit will be issued on products that are returned with no more than three (3) months remaining prior to expiration. Fifty percent (50%) credit will be issued on products that are returned within six (6) months after date of expiration. Product returned at any time prior to or after the Expiration Window that does not otherwise qualify for a return pursuant to this Return Policy will be destroyed by FUSA or its agent and no credit will be given to the buyer.

C. Additional Terms and Conditions of Return or Replacement

FUSA reserves the sole right to determine whether products qualify for return, credit, exchange or replacement pursuant to the terms of this Return Policy.

- Prior issuance of a Return Goods Authorization ("RGA") is required to return any products covered by this Return Policy. No credit, replacement or exchange will be issued without prior notification and authorization of the return. A letter, fax or email to the address below requesting such return and a copy of the original purchase order or invoices must be forwarded to FUSA with the product name, lot number, expiration date, and quantity being returned. Following receipt, review and approval of a request to return products, FUSA will provide a written RGA and instructions for the return of the product. Return requests received without the documentation referenced above will not be honored. RGAs are effective for thirty (30) days from the date of issuance.

Fresenius USA Marketing, Inc.  
920 Winter Street  
Waltham, MA 02451  
Fax: 781-699-9065  
Email: PharmaRGADept@fmc-na.com

- If returned goods are authorized for credit, such credit shall be effective for one (1) year from the date of issue, for the full amount of the price on the original invoice less any applicable price concessions, and if for expired products, such difference shall be further multiplied by the applicable percentages in Section II.B. No other remedy (including, but not limited to, incidental, consequential, or other damages of any kind) is available.
- Returns will not be accepted for overstocked products for any reason including, but not limited to, incorrectly placed orders or the buyer's inability to sell the products.
- Products eligible for return must be in original, unopened packages and must meet all criteria for individual product packaging listed in the exhibits to this Return Policy for the applicable product. The determination of the condition and count of any return products is within FUSA's sole discretion.
- Damaged merchandise must be accompanied by a signed receipt from the delivery carrier containing a description of all damage. In the absence of a signed receipt, the delivery carrier, not FUSA, shall be responsible for the damages.
- All returns must be on a freight-prepaid basis unless otherwise specified on the Return Goods Authorization form. FUSA is not responsible for payment of any processing fees.
- FUSA will not, under any circumstances, provide empty containers, empty labeled packages or loose labels for any purpose whatsoever.
- All returns must meet product specification requirements.
- Products provided at no charge are not eligible for credit.
- FUSA's Return Policy is subject to change at any time in FUSA's sole discretion without prior notification.

III. Non-Returnable Products

FUSA will not accept the following products for credit or return.

- Products which are not authorized for return or destruction or are outside the Expiration Window (as described above)
- Products which do not comply with the terms and conditions of this Return Policy.
- Products which are unlabeled or partially labeled, have defaced or covered labels, or lack valid or legible lot numbers or expiration dates.
- Products which were damaged by improper storage or by force majeure.
- Products which have been repackaged or relabeled.
- Products with broken seals, in open packages, or from which individual units have been removed from the original manufactured condition.
- Products which were sold on non-returnable terms.
- Products which are samples or donations.
- FUSA will not accept returns from third-party purchasers or end users, either directly from the third party purchaser or end user, or indirectly from the wholesaler.
- FUSA will not accept returns on product sold, purchased, distributed, prescribed or stored contrary to federal, state or local laws.

For RGAs or for more information concerning this Return Policy, please contact the Pharma RGA Department at 1-800-662-1237 x 101-3300.

Return Policy information is located at [www.freseniusmedicalcare.us](http://www.freseniusmedicalcare.us). Please check the website frequently because policies may change without notice.

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## EXHIBITS TO RETURN POLICY

### Exhibit: Venofer

Venofer is supplied sterile in 5 mL, and 2.5 mL single use vials. Each 5 mL vial contains 100 mg elemental iron, and each 2.5 mL vial contains 50 mg elemental iron (20 mg/mL).

NDC-49230-534-01	100 mg/5 mL	Single Use Vial Individually Boxed
NDC-49230-534-10	100 mg/5 mL	Single Use Vial Packages of 10
NDC-49230-534-25	100 mg/5 mL	Single Use Vial Packages of 25
NDC-49230-530-01	50 mg/2.5 mL	Single Use Vial Individually Boxed
NDC-49230-530-10	50 mg/2.5 mL	Single Use Vial Packages of 10
NDC-49230-530-25	50 mg/2.5 mL	Single Use Vial Packages of 25

### Exhibit: Velphoro

NDC-49230-064-51	500 mg chewable tablets	90 tablets per bottle
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### Exhibit: Phoslyra

NDC 49230-643-31	473 mL (16 fl. oz.) bottle	12 bottles per case
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### Exhibit: PhosLo

NDC 49230-640-21	Bottles of 200 Gelcaps	12 bottles per case
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