



Returned Goods Policy for ZILRETTA® Products
Effective June 1, 2023

General

This document sets forth terms and conditions that shall govern returns of ZILRETTA® (Triamcinolone Acetonide Extended-Release Injectable Suspension) to Pacira Pharmaceuticals, Inc. (“Pacira”) by customers who purchased ZILRETTA directly from Pacira (“Direct Customer”) and customers who purchased ZILRETTA directly from a Specialty Distributor (“SD Customer”). (“ZILRETTA Returned Goods Policy”).

Pacira may amend the ZILRETTA Returned Goods Policy from time to time without notice and without a customer’s consent. This ZILRETTA Returned Goods Policy supersedes and/or serves as notice of termination of any previous agreement or policy, whether written, oral, or established through course of dealing between Pacira and a customer with respect to the subject matter and ZILRETTA products (“Product(s)”).

I. RETURNS OF PRODUCT WITH MANUFACTURING DEFECTS PURCHASED BY DIRECT CUSTOMERS AND SD CUSTOMERS.

- a) **Returnable Products with Manufacturing Defects.** Products alleging the following manufacturing defects may be returned by Direct Customers and SD Customers for replacement Product:
- i) Products with deficiencies with the Product’s identity, quality, stability, reliability, safety, efficacy, performance, or usage after it is released for distribution (“Product Complaint” or “PC”); or
 - ii) Product where a device component (i.e., vial adapter) failed to meet its performance specifications or otherwise perform as intended (“Device Malfunction”).
 - iii) Reports of Product Complaints or Device Malfunctions should be reported to ProductComplaints@pacira.com and drugsafety@pacira.com. A Product Complaint or Device Malfunction report must include:
 - Physician Name;
 - Physician NPI;
 - Customer Shipping Address;
 - Lot Number;
 - Description of Product Complaint or Device Malfunction;

- Quantity of kits affected; and
 - Customer Contact Information.
- iv) Pacira reserves the right to determine, in its sole discretion, whether Product is eligible for replacement. Pacira may deem Products defective if any of the following criteria are met:
- Broken or damaged vial adaptor;
 - Punctured or otherwise damaged Product microsphere powder;
 - Punctured or otherwise damaged diluent;
 - Presence of debris or unidentified material in the ZILRETTA microsphere powder; and/or
 - Presence of debris or unidentified material in the diluent.

b) **Returns Process for Defective Product.** All requests from Direct Customers or SD Customers for Product returns and replacement related to Product Complaints or Device Malfunctions require prior authorization (“Returned Goods Authorization” or “RGA”) and must be obtained by contacting Pacira Customer Service at 1-855-803-9480 or PaciraReturns@ICSCconnect.com.

- i) The request for the RGA must include:
- Invoice/debit memo;
 - Customer contact name & phone number;
 - Detailed list of all applicable products, including:
 - o Product name;
 - o NDC number;
 - o Lot number;
 - o Expiration date;
 - o Quantity requested to be returned; and
 - o Reason for return;
 - Customer billing address;
 - Customer shipping address;
 - Return originator information (for batch returns, each return originator’s information must be provided), including:
 - o Name;
 - o Mailing address; and
 - o DEA number or HIN.
- ii) Once an RGA is approved by Pacira, the Customer must ship the Product to Pacira in a safe, secure, and reliable manner, and in compliance with all applicable federal, state, and local laws, regulations, and statutes. It is Customer’s responsibility to securely package all return Product to prevent breakage during transit and otherwise comply with laws and regulations. Broken Product containers that do not contain any viable product are NOT to be shipped to Pacira. Pacira is not responsible for returned goods lost and/or damaged in transit.
- All returned Product cartons must have affixed an RGA shipping label and must be clearly marked with the RGA number.

- An RGA issued by Pacira is based upon unconfirmed representations made to Pacira by Customer and is not intended to be a guarantee of credit or a basis for relying upon credit.
 - iii) Pacira does not accept collect returns. If the return is due to a Pacira shipping error, is damaged in-transit, or involves a manufacturing defect, Pacira will issue a prepaid call tag for the freight charges.
 - iv) Pacira will not credit or accept charges/deductions for administrative, handling, or freight charges associated with the return of Product to Pacira or any third-party returned goods processor.
 - v) Non-Pacira products returned to Pacira will not be returned to Customer and will not be the responsibility of Pacira.
 - vi) In no event is any Direct Customer or a SD Customer permitted to take a deduction for returned Products.
- c) **Replacement Product Shipments.** Replacement Products will be shipped to the Direct Customer or the SD Customer directly following the approval of the RGA by Pacira.

II. **PRODUCT RETURNS ELIGIBLE FOR CREDIT PURCHASED BY AN SD CUSTOMER**

Pacira reserves the right to determine, in its sole discretion, whether certain returned Product is eligible for credit. Products that are purchased by an SD Customer through a Specialty Distributor must follow the Specialty Distributor Returned Goods Policy and be returned through the Specialty Distributor for credit.

III. **PRODUCT RETURNS ELIGIBLE FOR CREDIT PURCHASED BY A DIRECT CUSTOMER**

- a) **Product Returns.** Pacira reserves the right to determine, in its sole discretion, whether certain returned Product is eligible for credit. In the event that Product returned by a Direct Customer for credit affects any discounts provided at the time of the Product purchase, Pacira will evaluate the impact of the return on the discount and calculate any financial impact on the credit.
- b) **Product Eligible for Credit.** The following returned goods may be eligible for credit:
- i) Expired Product returned within three (3) months past the expiration date. Product expiration occurs on the last day of the month of expiration noted on the product;
 - ii) Product returned due to Pacira's shipping error or due to the Product being damaged in-transit, if reported within five (5) business days of delivery; and
 - iii) Product returned at Pacira's request.
 - iv) Any other Product which Pacira determines is eligible for credit.

- c) **Returned Product Not Eligible for Credit.** Pacira reserves the right to decline credit and destroy returned Product, which Pacira determines, in its sole discretion, is not eligible for credit. Returned Product not eligible for credit includes, but is not limited to:
- i) Product not in its original container and/or not bearing its original label.
 - ii) Product returned prior to expiration. Product expiration occurs on the last day of the month of the expiration noted on the product.
 - iii) Product returned more than three (3) months past the product's expiration date.
 - iv) Product returned more than thirty (30) days after issuance of the RGA.
 - v) Product in which the lot number and/or expiration date is missing, illegible, covered, and/or unreadable.
 - vi) Partial returns, unless the returns originator is located in a state in which state law mandates credit to be issued for partial returns.
 - vii) Product that has been damaged subsequent to delivery due to improper storage or handling, exposure, or other circumstances beyond Pacira's control.
 - viii) Product that was sold expressly on a non-returnable basis.
 - ix) Product that is in its original container with a prescription label attached and/or container has been opened.
 - x) Product that has been repackaged, customer-specific labeled, or private labeled.
 - xi) Product distributed by Pacira at no charge, including professional samples.
 - xii) Product purchased on behalf of other manufacturers, institutions, contract research organizations, or others for use in clinical trials or studies, Phase IV studies, or for charitable donations.
 - xiii) Product obtained illegally or via diverted means.
 - xiv) Product that Pacira, in its sole discretion, determines is adulterated, misbranded, or counterfeit.
 - xv) Anything returned that is not a Pacira product.
- d) **Return Credits.** To be eligible for credit, the Direct Customer must return Product in its original container, bearing its original label and the lot number and expiration date must be legible. Credit returns will be handled as follows:
- i) Credit will be issued based on the number of units returned. Credits are intended to cover reimbursement for the net cost of the goods, and no other separate payments shall be provided otherwise.
 - ii) All credits will be paid via credit memo. Credits must be redeemed within one (1) year of issuance or will be void thereafter.
 - iii) Any right of deduction or set-off for returned goods shipments may only be exercised by Customer following receipt of a properly issued credit memo. IN NO EVENT IS ANY CUSTOMER PERMITTED TO TAKE A DEDUCTION FOR RETURNED PRODUCTS WITHOUT A PROPERLY ISSUED CREDIT MEMO.

- iv) Products that are eligible for credit will be credited at the lower of (a) lowest historical invoice price for which that specific lot number was sold by Pacira, or (b) the lowest historical contract price in effect for the return originator for that specific lot number, which shall be net of credits, discounts, and rebates.
- v) Products returned at Pacira's request will be credited at the lower of (a) current wholesale acquisition cost, or (b) current contract price for the return originator.
- vi) Non-Pacira products returned to Pacira will not be returned back to a customer and will not be the responsibility of Pacira.