

# ADSTILADRIN Product Replacement Policy

This document outlines Ferring Pharmaceuticals Inc.'s ("Ferring") policy regarding requests made by healthcare professionals and/or Sites-of-care for replacement of an Adstiladrin unit either (a) purchased directly from Ferring or an authorized distributor of record of Ferring (each, an **"Authorized Distributor"**) or (b) received by such site-of-care without charge from Ferring or its third-party vendors as Product under an Ferring Patient Assistance Program or (c) Dispensed from a specialty pharmacy that purchased directly from Ferring.

## 1. Eligibility Criteria for Replacement:

- Ferring **reserves the sole right** to determine whether the request qualifies for replacement.
- Expired Products (i.e., if the Expiration Date on the package/container has passed) **are not** eligible for replacement.
- A site-of-care's failure to handle Product properly (or intentional mishandling) **is not** grounds for replacement.
- Product that becomes damaged or defective after receipt at the site-of-care will be considered for replacement **on a case-by-case basis**.
- All Product replacement requests by Authorized Distributors, third-party processors and/or similar entities which are not sites-of-care **will be declined**.

## 2. Product Prepared and not Administered to Patient:

- Product prepared for administration to a patient may be considered eligible for replacement if:
  - Product was prepared in anticipation of administration to a patient, as directed per Adstiladrin package insert, prior to patient's arrival at the site-of-care and was not administered due to patient's refusal, even though patient previously consented to administration; **OR**
  - Subsequent clinical factors (e.g., change in health status) emerged post-preparation of the Product for administration, which were absent at the time of patient consent of Product administration.

## 3. Product Administered to Patient:

- Product administered to a patient may be considered eligible for replacement if:
  - Administration of product happened before July 31, 2025
  - Site-of-Care followed the prescribing information recommendation of pre-treatment of patient with anticholinergics or similar premedication to prevent bladder spasm; **AND**
  - A patient is observed to have significant expulsion of the drug within 10 minutes of a 75 ml ADSTILADRIN instillation to the bladder, documented by ultrasound showing less than 25 ml's residual fluid in the bladder.
  - Upon replacement decision original product (or what is remaining) will be destroyed within 24 hours.

## 4. Additional Requirements:

- All Product subject to a replacement request:
  - Must have been properly stored and handled by the site-of-care.
  - Must not be damaged from such perils as are normally insured, including but not limited to, vandalism, malicious mischief, natural disaster, and improper storage.
  - Must have been purchased directly from Ferring or an Authorized Distributor or dispensed from a specialty pharmacy that purchased directly from Ferring.
  - Site-of-care must certify that it will not submit a claim for commercial **OR** government insurance for reimbursement, nor will it seek reimbursement for a cash payment, including in the form of a patient copayment or deductible, for both the original Product and the replacement Product.
  - If Product was provided without charge from Ferring or its third-party vendors such as Product under a Ferring Patient Assistance Program (PAP), Site-of-Care must certify that no commercial or government insurance claim for reimbursement will be processed, nor will cash payment be sought or collected, including in the form of a patient copayment or deductible, for either the original Product or the replacement Product.

## 5. Process and Form Submission:

- Each requesting Site-of-Care must complete an Adstiladrin Product Replacement Form within seven (7) calendar days of the incident. Original Product or any unused portion subject to the replacement request must be retained by the Site-of-care until receiving further instruction from Ferring.

**6. Adstiladrin Product Replacement Policy** is subject to change at any time at Ferring's sole discretion and without prior notice.