

TRODELVY® Spoilage Replacement Program

Trade Operations: 1-800-939-9009

Only FDA-approved indications will be considered for replacement.

If TRODELVY is purchased for use for an FDA-approved indication, was spoiled, and all eligibility requirements are met, the product may be eligible for replacement through the TRODELVY Spoilage Replacement Program. Product must be returned or Certificate of Destruction must be furnished to be eligible for the TRODELVY Spoilage Replacement Program.

For quality or stability-related issues, please contact Gilead Medical Information at 1-866-633-4474.

For expired product returns, please contact Gilead Trade Operations at 1-800-939-9009.

Eligibility criteria

- In order to be eligible for replacement, TRODELVY must have been spoiled or rendered unusable (“Spoiled Product”) after purchase by a licensed healthcare provider (“HCP”) because:
 - The TRODELVY vial was mishandled, dropped, or broken by the HCP;
 - TRODELVY was inappropriately stored or refrigerated due to a catastrophic event or redundant system failure;
 - TRODELVY was reconstituted but not administered to the patient due to an unforeseen patient condition or because the patient missed the appointment; or
 - There was an error during mixing.
- The Spoiled Product was prescribed for an FDA-approved indication
- NO portion of the Spoiled Product has been administered and NO portion of the Spoiled Product is intended to be administered to any patient
- The Spoiled Product was purchased from a TRODELVY authorized distributor
- The HCP has not billed and will not bill for or receive any payment from a payer or patient for any portion of the Spoiled Product

Process and form completion

- Each spoilage incident must be reported separately by completing the Spoilage Replacement Form <https://www.gilead.com/-/media/files/pdfs/other/TRODELVY-Spoilage-Replacement-Program-Form.pdf>
- Attestation must be provided at the end of the Spoilage Replacement Form by a HCP who has signing authority for the facility
- E-mail completed Spoilage Replacement Forms to ordersccs@gilead.com within thirty (30) calendar days of spoilage; the date of spoilage incident will be required to submit the form

- If approved, a Return Authorization form containing further instructions for returning product or completing a Certificate of Destruction will be provided within five (5) business days of the form submission
- To avoid any delays, ensure that the Return Authorization form is included with any product being sent back
- Send one Return Authorization form per return package
- If you have questions or would prefer a paper form to fax, please call Gilead Trade Operations at 1-800-939-9009
- If needed, Gilead Trade Operations is available to answer questions regarding the Spoilage Replacement Form

Important program guidelines

- Each instance of spoilage requires completion of this form and pictures of Spoiled Product, where applicable
- Gilead will determine whether to provide replacement of Spoiled Product on a case-by-case basis
- Please retain all original product and packaging and return Spoiled Product in accordance with the instructions provided on the Return Authorization form
- Gilead can ship replacement product only to licensed healthcare facilities
- Requests are subject to certain limitations and conditions
 - HCP does not have insurance policy coverage that covers the replacement of the Spoiled Product
 - For replacement requests due to mishandled, dropped, or broken vials; reconstituted product not administered to a patient due to an unforeseen patient condition or patient missed appointment; or mixing errors, each instance of replacement is limited to the actual number of vials affected (but in no instance greater than eight (8) vials)
 - The total number of Spoiled Product replacements in any twelve (12) month period is limited to three (3) replacements per site
 - For replacement requests due to inappropriate storage or refrigeration due to a catastrophic event or redundant system failure, each instance of replacement is limited to the actual number of vials affected (but in no instance greater than the number of vials purchased through an authorized distributor by the site in the last seven (7) calendar days)
 - The total number of Spoiled Product replacements in any twelve (12) month period is limited to one (1) replacement per site

Gilead retains the right to make the final decision regarding any spoilage replacement request. All spoilage requests are subject to review. Returned product is subject to analysis.

Gilead has the right to modify or discontinue the TRODELVY Spoilage Replacement Program at any time without notice.