



Heron Product Replacement Policy Overview

Heron Therapeutics is pleased to offer a product replacement program to healthcare providers or direct purchasing customers under the following circumstances: **wastage and breakage, product complaints, or expired product.**

Heron Therapeutics will, in its sole discretion and judgment, consider all justifiable requests for replacement of SUSTOL or CINVANTI. Heron Therapeutics will replace SUSTOL or CINVANTI providing one or more of the conditions stated below are met. Such requests are subject to Heron Therapeutics approval.

Heron Therapeutics requires an authorization for each unit of SUSTOL or CINVANTI to be replaced.

Please follow the following steps to ensure product replacement requests are processed appropriately:

1 **Contact Heron Connect at 1-844-HERON11 (1-844-437-6611)** to initiate the product replacement request. For requests due to wastage or breakage and product complaints, **requests should be within one week of the occurrence.**

2 If the request meets the defined criteria (please see replacement conditions below), the practice will complete a **Letter of Affiliation (LOA)** and submit their Medical license.

The LOA will be provided by Heron Connect.

Timing: Product replacement requests will be processed within 7-10 business days.



Wastage and Breakage

Products returned due to wastage and breakage, including product that is mishandled at the site of care (e.g., syringe dropped, refrigerator malfunction) and is deemed not useable for patient treatment, may be considered for product replacement. This situation is not reported as a product complaint but rather user error.

A unit of SUSTOL or CINVANTI may be considered for replacement under this section if it meets one or more of the following conditions:

- The SUSTOL needle was lost or was dropped, creating a concern regarding sterility
- The SUSTOL syringe was dropped or broken
- SUSTOL remained at room temperature for more than 7 days
- CINVANTI remained at room temperature for more than 60 days
- CINVANTI vial was dropped or broken
- CINVANTI was diluted but not administered within the stability guidelines defined in the Prescribing Information (PI)

Call 1-844-HERON11 (1-844-437-6611) from 8 AM to 8 PM ET, Monday through Friday.

Please see accompanying full Prescribing Information for CINVANTI and SUSTOL.

For more information, please see reverse side.





Product Complaint*

A unit of SUSTOL or CINVANTI may be considered for replacement due to product complaint if it meets one or more of the following:

- Physical defect in the product
- Mechanical defect in the product
- Physical defect in packaging or labeling

***Heron Therapeutics Quality Assurance (QA) will provide direction for the return of the SUSTOL or CINVANTI unit due to product complaint.**



Expired Product

A unit of SUSTOL or CINVANTI may be considered for replacement if it remains unused past the expiration date included on product packaging.

Additional Notes

This policy is effective December 1, 2017.

Product credits will not be issued for product eligible for replacement under this policy.

Replacement units will consist of a full unit. In the case of SUSTOL this will include a full kit containing:

- One sterile single-dose amber colored glass syringe which contains 10mg granisetron/0.4 mL
- One sterile 18 Ga 5/8" special thin walled administration needle
- Two sodium acetate syringe warming pouches
- One Point Lok needle protection device

Replacement SUSTOL administration needles will not be sent outside of a full replacement unit of SUSTOL.

Unless requested by Heron Therapeutics QA to return the product, Providers receiving replacement units of SUSTOL or CINVANTI should dispose of the unused product in a responsible manner consistent with their standard practices for disposing of unused medication and materials.

For information regarding returns of SUSTOL or CINVANTI damaged during shipping, please see the Direct Purchaser or Provider Returned Goods policy.

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Please see accompanying full Prescribing Information for CINVANTI and SUSTOL.