HERON THERAPEUTICS PRODUCT REPLACEMENT POLICY

sustol® (granisetron) extended-release injection

CINVANTI® (aprepitant) injectable emulsion

APONVIE™ (aprepitant) injectable emulsion

ZYNRELEF® (bupivacaine and meloxicam) extended-release solution
29.25 mg/mL and 0.88 mg/mL

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

REPLACEMENT CONDITIONS

Heron Therapeutics requires an authorization for each unit of SUSTOL, CINVANTI, APONVIE, or ZYNRELEF to be replaced. **To qualify for a Wastage and Breakage or Product Complaint replacement, contact Heron Therapeutics at 1-844-HERON11 (1-844-437-6611) within one week of the occurrence.** Replacement requests will be processed within 7 to 10 business days. Heron Connect is available to address replacement requests from 8 AM to 5 PM ET, Monday through Friday.

HERON CONNECT®

Wastage and Breakage

Products returned due to wastage and breakage include products that are mishandled at the site of care (eg, syringe dropped, refrigerator malfunction) and deemed not usable for patient treatment. This situation is not reported as a product complaint but rather user error.

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

- Refrigerator malfunction for refrigerated product (SUSTOL or CINVANTI)
- The SUSTOL needle was lost or was dropped, creating a concern regarding sterility
- The SUSTOL syringe was dropped during preparation or administration
- SUSTOL remained at room temperature for more than 7 days
- CINVANTI remained at room temperature for more than 60 days
- The CINVANTI vial was dropped during preparation or administration
- CINVANTI was diluted but not administered within the stability guidelines defined in the Prescribing Information (PI)
- The ZYNRELEF vial was dropped, broken, or damaged by the user

Note: ZYNRELEF component parts, listed below, which are dropped, broken, damaged, or mishandled during preparation, will not be replaced as part of this policy. This includes situations where the mishandling of the components results in concern about component sterility. If additional component parts are needed, users will be directed to their wholesaler or specialty distributor to obtain replacement components.

- Vented vial spike
- 12-mL Luer lock syringe
- Luer lock applicator

Note: Syringe tip caps will not be distributed by the wholesaler/distributor as a replacement component. They will only be included in the original kit.

Please see full Prescribing Information for ZYNRELEF, including Boxed Warning.

Product Complaint

A unit of SUSTOL® (granisetron), CINVANTI® (aprepitant), APONVIE™ (aprepitant), or ZYNRELEF® (bupivacaine and meloxicam) may be considered for replacement due to product complaint if it meets one or more of the following:

- Physical defect in the product or the components included in the kit
  - These defects should be reported no more than 30 days after product purchase
- Mechanical defect in the product
- Physical defect in packaging or labeling
- ZYNRELEF or SUSTOL component part was missing from the product kit or arrived damaged

Retain the complaint product of the SUSTOL, CINVANTI, APONVIE, or ZYNRELEF unit until Heron Therapeutics Quality Assurance (QA) contacts you with further instruction.

Expired Product

Providers will be directed to contact their wholesaler or specialty distributor to discuss product credit or replacement for the expired product.

If no option exists through the wholesaler or specialty distributor, a unit of SUSTOL, CINVANTI, APONVIE, or ZYNRELEF may be considered for replacement for up to twelve (12) months past the expiration date on product packaging if it remains unused and has a valid Heron lot number and expiry date.

Additional Notes

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

In the case of SUSTOL, the replacement will include a full kit containing:

- One sterile single-dose, amber-colored glass syringe that contains 10 mg 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.

In the case of CINVANTI, a single replacement unit will be provided.

In the case of APONVIE, the replacement will include a full carton (10 single-dose vials).

In the case of ZYNRELEF, if vial issues arise, the replacement product will include a full kit containing:

Product Presentation				Vented Vial Spike Provided	Luer Lock Syringe(s) Provided	Luer Lock Applicator(s) Provided	Syringe Tip Cap(s) Provided
NDC	Bupivacaine/ Meloxicam	Volume	Vial Size				
47426-301-02	400 mg/12 mg	14 mL	20 mL	1	2 (12 mL)	2	2
47426-303-01	200 mg/6 mg	7 mL	10 mL	1	1 (12 mL)	1	1

If the component parts are damaged or missing, upon receipt, from a purchased kit, a Product Complaint will be reported and the entire ZYNRELEF kit is eligible for replacement.

Unless product is associated with a Product Complaint, providers receiving replacement units of SUSTOL, CINVANTI, APONVIE, or ZYNRELEF 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, CINVANTI, APONVIE, or ZYNRELEF damaged during shipping, please contact the authorized wholesaler or specialty distributor.

Please see full Prescribing Information for ZYNRELEF, including Boxed Warning.

HeronConnect.com

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