SUSTOL® (granisetron) extended-release injection

Distribution Reference Guide

SUSTOL is the first and only 5-hydroxytryptamine3 (5-HT3) receptor antagonist with advanced extended-release technology and proven 5-day chemotherapy-induced nausea and vomiting (CINV) protection*.[1-6]

*SUSTOL is indicated for the prevention of CINV due to MEC and AC combination chemotherapy.[1]

Supplied and marketed by: Heron Therapeutics, Inc.

Product name: SUSTOL

Established name: (granisetron) extended-release injection

SUSTOL pricing is based on wholesale acquisition cost (WAC). WAC is subject to change without notice. WAC is the list price to wholesalers for SUSTOL, without taking into account any terms specific to wholesalers, such as prompt payment terms, introductory launch terms, other discounts or chargebacks.

Distributor Name	Website	Phone
Oncology Practices:		
• Cardinal Health Specialty Pharmaceutical Distribution	http://specialtyonline.cardinalhealth.com	1-866-677-4844
• McKesson Specialty	https://mscs.mckesson.com	1-800-482-6700
• Oncology Supply	www.oncologysupply.com	1-800-633-7555
Hospitals:		
• ASD Healthcare	www.asdhealthcare.com	1-800-746-6273
• Cardinal Health Specialty Pharmaceutical Distribution	http://specialtyonline.cardinalhealth.com	1-866-677-4844
• McKesson Plasma and Biologics	https://connect.mckesson.com	1-877-625-2566

To help support the traditional claims processing timeline of newly approved products, ask your preferred distributor about extending dating terms.

Indication

SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

Important Safety Information

Contraindications

SUSTOL is contraindicated in patients with hypersensitivity to granisetron, any of the components of SUSTOL, or any other 5-HT3 receptor antagonist.

Warnings and Precautions

Injection site reactions (ISRs), including infection, bleeding, pain and tenderness, nodules, swelling, and induration, have occurred with SUSTOL. Monitor for ISRs following SUSTOL injection. Inform patients that some ISRs may occur 2 weeks or more after SUSTOL administration. In patients receiving antiplatelet agents or anticoagulants, consider the increased risk of bruising or severe hematoma prior to the use of SUSTOL.

Monitor for constipation and decreased bowel activity and consider optimizing patients' current bowel regimens used for managing preexisting constipation. Instruct patients to seek immediate medical care if signs and symptoms of ileus occur.

Hypersensitivity reactions have been reported and may occur up to 7 days or longer following SUSTOL administration and may have an extended course. If a reaction occurs, administer appropriate treatment and monitor until signs and symptoms resolve.

Serotonin syndrome has been reported with 5-HT3 receptor antagonists alone but particularly with concomitant use of serotonergic drugs.

Use in Specific Populations

Avoid SUSTOL in patients with severe renal impairment. In patients with moderate renal impairment, administer SUSTOL not more frequently than once every 14 days.

Adverse Reactions

Most common adverse reactions (≥3%) are injection site reactions, constipation, fatigue, headache, diarrhea, abdominal pain, insomnia, dyspepsia, dizziness, asthenia, and gastroesophageal reflux.

Report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
Report side effects to Heron at 1-844-437-6611.

Please see accompanying full Prescribing Information including Medication Guide or visit www.SUSTOL.com.

sustol®
(granisetron) extended-release injection

Package Information: SUSTOL®

Product code	Description	Quantity of single-dose kits in package
NDC 47426-101-06 For payers requiring physicians to report 11-digit NDCs when reporting a drug on a claim form, please use the 11-digit code below: NDC 47426-**0101**-06	**One single-dose kit containing:** • One sterile, single-dose, amber colored glass syringe which 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, • Instructions for Use, Prescribing Information, and Medication Guide	One single-dose kit

SUSTOL is available in a carton of 6 single-dose kits or in shipping cases containing 4 cartons of 6 kits (24 kits total). Refer to your preferred distributor for ordering information.

Package Dimensions

Single-unit kit		Carton (6 single-dose kits)		Shipper (4 cartons [24 single-dose kits])	
Length (in)	4"	Length (in)	12 ¼"	Length (in)	15"
Width (in)	1 13/16"	Width (in)	3 ¾"	Width (in)	12 ½"
Height (in)	7"	Height (in)	7 ¼"	Height (in)	7 ¾"

Storage and Handling

Store SUSTOL in the refrigerator at 2° C to 8° C (36° F to 46° F).
SUSTOL can be placed back in the refrigerator after being kept at room temperature. SUSTOL can remain at room temperature for up to a maximum of 7 days.
Protect from light. Do not freeze.[1]

Heron Connect™

A fully integrated reimbursement and patient support program that provides practices with a dedicated team of Reimbursement Counselors.

Drug replacement

In the event that SUSTOL is determined to be unfit for patient use* or has expired, Heron Therapeutics will replace the affected units.

– Contact Heron Connect at **1-844-HERON11 (1-844-437-6611)** from 8 AM to 8 PM ET, Monday through Friday

Heron Commitment Program†

Credits the practice for the cost of Heron products in the event of a qualifying claim denial, when program requirements are met.†‡

*Determination will be made by the manufacturer of SUSTOL.

†The Heron Commitment Program and the other product support programs offered by Heron Therapeutics do not impose any purchase obligation at any time or in any manner. Use of SUSTOL may be discontinued at any time, without penalty.

‡A qualifying claim denial can be reviewed for the Heron Commitment Program when, for a patient covered under commercial insurance, the following criteria have been met, and documentation confirms: (a) the verification of benefits, conducted by the provider and/or Heron Connect, meets all of the payer criteria and/or policy requirements, (b) the submitted claim for the Heron product is denied, and (c) the claim has been denied again by the commercial payer after the first level of appeals process has been followed.

Please see Indication and Important Safety Information on reverse side and accompanying Full Prescribing Information.

References: 1. SUSTOL [package insert]. Heron Therapeutics, Inc., San Diego, CA; June 2019. **2.** Aloxi® [package insert]. Woodcliff Lake, NJ: Eisai Inc; December 2015. **3.** Zofran® [package insert]. Research Triangle Park, NC: GlaxoSmithKline; March 2017. **4.** Kytril® [package insert]. South San Francisco, CA: Genentech, Inc; April 2011. **5.** Sancuso® [package insert]. Bridgewater, NJ: ProStrakan Inc; January 2017. **6.** Anzemet® [package insert]. Bridgewater, NJ: Sanofi-Aventis; September 2014.

If you have any distribution-related questions, please contact your account manager or call Heron Connect at **1-844-HERON11 (1-844-437-6611)** from 8 AM to 8 PM ET, Monday through Friday. You can also visit **sustol.com**.

 08/19 PP-SL-0075 **www.sustol.com**

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