



Sustol[®] (granisetron) – New Drug Approval

- On August 10, 2016, [Heron Therapeutics announced](#) the [FDA approval](#) of [Sustol \(granisetron\)](#) extended-release injection, 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.
- Sustol is a serotonin-3 (5-HT₃) receptor antagonist. By binding to 5-HT₃ receptors, Sustol blocks serotonin stimulation and subsequent vomiting after chemotherapy.
- The efficacy of Sustol was based on a randomized, non-inferiority study of 733 patients comparing Sustol to [Aloxi[®] \(palonosetron\)](#) injection. The primary endpoints were proportion of patients with complete response (CR) [defined as no emetic episodes and no use of rescue medication] during the acute phase (0 to 24 hours) and the delayed phase (> 24 to 120 hours) following the administration of chemotherapy in cycle 1.
 - Non-inferiority of Sustol to Aloxi was demonstrated in the acute and delayed phases of MEC and of AC combination chemotherapy.
- Contraindications of Sustol include hypersensitivity to granisetron, any of the components of Sustol, or any of the other 5-HT₃ receptor antagonists.
- Warnings and precautions of Sustol include injection site reactions, gastrointestinal disorders, hypersensitivity reactions, and serotonin syndrome.
- The most common adverse events (≥ 3%) with Sustol use were injection site reactions, constipation, fatigue, headache, diarrhea, abdominal pain, insomnia, dyspepsia, dizziness, asthenia, and gastroesophageal reflux.
- The recommended dose of Sustol is 10 mg administered as a single subcutaneous injection by a healthcare provider at least 30 minutes before the start of emetogenic chemotherapy on day 1.
 - Sustol should not be administered more frequently than once every 7 days.
 - Use of Sustol with successive emetogenic chemotherapy cycles for > 6 months is not recommended.
 - In combination with dexamethasone, Sustol should be given at least 30 minutes before the initiation of MEC or AC combination chemotherapy
 - If Sustol is administered with an NK₁ receptor antagonist, see the prescribing information of the NK₁ receptor antagonist for the recommended dexamethasone dosage.
- Granisetron is also generically available as an [intravenous injection](#) and as [oral tablets](#). Brand [Sancuso[®] \(granisetron\)](#) is available as a transdermal patch.
- Heron Therapeutics plans to launch Sustol in the fourth quarter of 2016. Sustol will be available as an extended-release injection of 10 mg/0.4 mL in a single-dose, pre-filled syringe.



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