

MEDICATION GUIDE

SUSTOL® (sus' tol)
(granisetron)

extended-release injection, for subcutaneous use

What is the most important information I should know about SUSTOL?

SUSTOL can cause serious side effects, including:

- **Injection site reactions.** Some injection site reactions may be serious and require medical care. Injection site reactions may include infections, bruising, swelling that is caused by blood that collects under the skin (hematoma), bleeding, pain and tenderness, and small bumps (nodules) at the injection site. Infections, bruising, and hematomas can happen up to 2 weeks or more after receiving SUSTOL.

Tell your healthcare provider if you have:

- pain or tenderness that you need to take pain medicine for or if you have pain that interferes with your daily activity.
- bruising, hematoma, or a nodule at the injection site that does not go away. Your risk of severe bruising and hematomas at the injection site is increased if you take a blood thinner medicine (anticoagulant or antiplatelet medicine).

Get medical care right away if you have:

- signs of an infection at the injection site, including redness or warmth, or if you have a fever.
- bleeding at the injection site that is severe or lasts for longer than 24 hours.

- **Stomach and intestinal problems.** Problems having a bowel movement (constipation) that may be serious, can happen up to 7 days after treatment with SUSTOL. These problems may be more likely in people taking opioid pain medicines. SUSTOL can make it harder to identify certain stomach and bowel problems you may have. Tell your healthcare provider if you have constipation or your constipation worsens after you receive SUSTOL. Get medical care right away if you have pain or swelling in your stomach-area (abdomen).

- **Serious allergic reactions.** Serious allergic reactions have happened in people who receive SUSTOL and who have had allergic reactions to other medicines used to help prevent nausea and vomiting called 5-HT₃ receptor antagonists. Serious allergic reactions can happen up to 7 days or longer after treatment. Get emergency medical help right away if you have any signs or symptoms of a serious allergic reaction, including:

- hives
- swollen face
- breathing trouble
- chest pain

What is SUSTOL?

- SUSTOL is a prescription medicine called an “antiemetic.”
- SUSTOL is used in adults to help prevent the nausea and vomiting that happens right away or later with certain anti-cancer medicines (chemotherapy).

It is not known if SUSTOL is safe and effective in children under 18 years of age.

Who should not receive SUSTOL?

Do not receive SUSTOL if you are allergic to:

- granisetron or any of the ingredients in SUSTOL. See the end of this Medication Guide for a complete list of ingredients in SUSTOL.
- any other 5-HT₃ receptor antagonist medicine used to help prevent nausea and vomiting.

What should I tell my healthcare provider before receiving SUSTOL?

Before receiving SUSTOL, tell your healthcare provider about all of your medical conditions, including if you:

- have constipation
- have had recent stomach-area (abdominal) surgery
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if SUSTOL will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SUSTOL passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you will receive SUSTOL.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using SUSTOL with certain other medicines can cause serious side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How will I receive SUSTOL?

- SUSTOL will be given to you by an injection under your skin (subcutaneously) in the back of your upper arm or in your stomach-area (abdomen) on Day 1 of your chemotherapy cycle.
- SUSTOL will be given to you by a healthcare provider.
- SUSTOL is usually given about 30 minutes before you receive your anti-cancer medicine (chemotherapy).
- You should not receive SUSTOL more often than 1 time every 7 days.

What are the possible side effects of SUSTOL?

SUSTOL may cause serious side effects, including:

- See “What is the most important information I should know about SUSTOL?”
- **Serotonin Syndrome.** A possible life-threatening problem called serotonin syndrome can happen with medicines called 5-HT₃ receptor antagonists, including SUSTOL, especially when used with medicines used to treat depression and migraine headaches called serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs), and certain other medicines. Tell your healthcare provider or nurse right away if you have any of the following symptoms of serotonin syndrome:
 - agitation, seeing things that are not there (hallucinations), confusion, or coma
 - fast heartbeat or unusual and frequent changes in your blood pressure
 - dizziness, sweating, flushing, or fever
 - tremors, stiff muscles, muscle twitching, overactive reflexes, or loss of coordination
 - seizures
 - nausea, vomiting, or diarrhea

The most common side effects of SUSTOL include: injection site reactions, constipation, fatigue, headache, diarrhea, stomach-area (abdominal) pain, trouble sleeping or falling asleep, indigestion, dizziness, weakness, and heartburn.

These are not all the possible side effects of SUSTOL. Tell your healthcare provider if you have any side effect that bothers you or does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General Information about the safe and effective use of SUSTOL

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SUSTOL for a condition for which it was not prescribed. Do not give SUSTOL to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about SUSTOL that is written for health professionals.

What are the ingredients in SUSTOL?

Active ingredient: granisetron

Inactive ingredients: triethylene glycol poly(orthoester) polymer and polyethylene glycol monomethyl ether

Manufactured by: Lifecore Biomedical, Chaska, MN 55318

Marketed by: Heron Therapeutics, Inc., Redwood City, CA 94063

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For more information, go to www.SUSTOL.com or call 1-844-437-6611.

This Medication Guide has been approved by the U.S. Food and Drug Administration

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