

Patient Information
SANCUSO® [san-KOO-so]
(granisetron transdermal system)
for transdermal use

Important: For skin use only.

Read the Patient Information that comes with SANCUSO before you start using it and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment. If you have any questions about SANCUSO, ask your healthcare provider.

What is SANCUSO?

SANCUSO is a prescription medicine used to prevent nausea and vomiting in adults receiving anti-cancer (chemotherapy) treatment that causes moderate or severe vomiting.

SANCUSO is a skin patch (transdermal system) that slowly releases the medicine into your bloodstream while you wear the transdermal system.

It is not known if SANCUSO is safe and effective in children.

Who should not use SANCUSO?

Do not use SANCUSO if you are allergic to granisetron or any of the ingredients in SANCUSO. See the end of this leaflet for a list of ingredients in SANCUSO.

What should I tell my healthcare provider before using SANCUSO? Before using SANCUSO, tell your healthcare provider about all of your medical conditions, including if you:

- have pain or swelling in your stomach area (abdomen).
- are pregnant. It is not known if SANCUSO will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if SANCUSO passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Other medicines may affect how SANCUSO works. SANCUSO may also affect how other medicines work. SANCUSO contains granisetron. Do not take other granisetron containing products with SANCUSO.

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

How should I use SANCUSO?

- Read the Instructions for Use that comes with SANCUSO transdermal system.
- Use SANCUSO exactly as your healthcare provider tells you to.

What should I avoid while using SANCUSO?

Do not apply any heat source over or near the SANCUSO transdermal system.

- A heating pad or heat lamp should not be used where the transdermal system is applied.
- You should avoid long periods of exposure to heat because heat can increase the amount of SANCUSO in your blood.
- **Avoid sunlight and artificial sunlight.** The medicine in SANCUSO may not work as well and may affect your skin if exposed to direct sunlight or artificial sunlight from sunlamps or tanning beds.
- Keep the transdermal system covered with clothing if you will be in direct sunlight or artificial sunlight.
- Keep the skin where SANCUSO was applied covered for another 10 days after the transdermal system is taken off to protect from exposure to direct sunlight or artificial sunlight.

What are the possible side effects of SANCUSO?

SANCUSO may cause serious side effects, including:

- **Using SANCUSO may make it harder to identify certain stomach (abdomen) and bowel problems that are from other causes.** Tell your healthcare provider if you have any abdominal pain or swelling while using SANCUSO.

- **Serotonin Syndrome.** A potentially life-threatening problem called serotonin syndrome can happen if you use SANCUSO with certain medicines. **Call your healthcare provider or go to the nearest hospital emergency room right away** if you have any of the following signs and symptoms of serotonin syndrome:
 - agitation
 - seeing or hearing things that are not real (hallucinations)
 - confusion
 - coma
 - fast heart beat
 - changes in blood pressure
 - dizziness
 - sweating
 - flushing
 - high body temperature (hyperthermia)
 - shaking (tremors), stiff muscles, or muscle twitching
 - loss of coordination
 - seizures
 - nausea, vomiting, diarrhea
- **Skin reactions.** Skin reactions can happen at the transdermal system application site or outside the transdermal system application site. Tell your healthcare provider if you get any redness, rashes, bumps, blisters or itching at or near the transdermal system application site, and especially if they spread outside the place where the transdermal system was applied or if they appear outside the transdermal system application site. You may need to stop using SANCUSO.

The most common side effects of SANCUSO include:

- constipation

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of SANCUSO. For more information, ask your healthcare provider or pharmacist.

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

How should I store SANCUSO?

- Store SANCUSO at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep SANCUSO in the original package it comes in.

Keep SANCUSO out of the reach of children.

General information about the safe and effective use of SANCUSO.

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

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For more information, go to www.sancuso.com or call 1-833-SANCUSO.

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This Patient Information has been approved by the U.S. Food and Drug Administration

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