

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.

Manufactured by:
Kindeva Drug Delivery L.P.
Northridge, CA 91324

Manufactured for:
Cumberland Pharmaceuticals Inc.
Nashville, TN 37203

For more information, go to www.sancuso.com or call 1-877-683-6110.

Instructions for Use
SANCUSO® [san-KOO-so]
(granisetron transdermal system)
for transdermal use

Read this Instructions for Use before you start using SANCUSO transdermal system 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 treatment.

Important Information:

- SANCUSO is for skin use only (transdermal system).
- Avoid exposing the SANCUSO transdermal system application site to direct heat sources such as a heating pad or heat lamp.
- Avoid exposing the SANCUSO transdermal system to direct sunlight or artificial light such as a sunlamp or tanning bed.
- Keep the SANCUSO transdermal system covered with clothing if you will be in sunlight or artificial sunlight.
- Keep the skin where the SANCUSO transdermal system was applied covered for another 10 days after the SANCUSO transdermal system is taken off, to protect from exposure to direct sunlight or artificial sunlight.
- Skin reactions can happen at the SANCUSO transdermal system application site or outside the SANCUSO transdermal system application site. Tell your healthcare provider if you get any redness, rashes, bumps, blisters or itching at the SANCUSO transdermal system application site, and especially if they spread outside the place where the SANCUSO transdermal system was applied or if they appear outside the SANCUSO transdermal system application site. You may need to stop using the SANCUSO transdermal system.

How should I store the SANCUSO transdermal system?

- Store the SANCUSO transdermal system at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the SANCUSO transdermal system in the original package it comes in.
- Do not open the package until you are ready to apply the SANCUSO transdermal system.

Supplies:

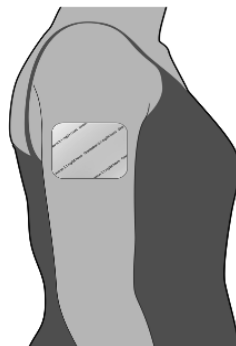
- SANCUSO transdermal system
- surgical or medical adhesive tape (not included)

When do I apply the SANCUSO transdermal system?

- Use the SANCUSO transdermal system exactly as your healthcare provider tells you to.
- Apply the SANCUSO transdermal system at least 1 day (24 hours) or up to 2 days (48 hours) before your scheduled anti-cancer (chemotherapy) treatment.
- Wear the SANCUSO transdermal system all the time during your chemotherapy treatment.
- Wait at least 1 day (24 hours) after your chemotherapy treatment is finished to remove the SANCUSO transdermal system.
- The SANCUSO transdermal system may be worn for up to 7 days.

Where do I apply the SANCUSO transdermal system?

- SANCUSO transdermal system should only be applied to the outside of the upper arm.
- Apply the SANCUSO transdermal system to a clean, dry, nearly hairless, healthy area of skin on the outside part of your upper arm. If there is hair, do not shave. Instead, clip hair as close to the skin as possible.



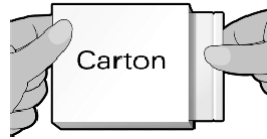
- The area you choose should not be oily or recently shaved. The SANCUSO transdermal system should not be placed on skin that is red, irritated, or damaged (cut or scraped).

- **Do not** apply the SANCUSO transdermal system to areas that have been treated with creams, oils, lotions, powders or other skin products that could keep the SANCUSO transdermal system from sticking well to your skin.

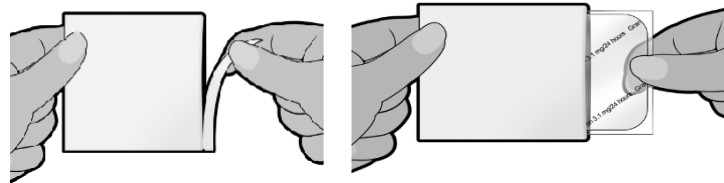
How do I apply the SANCUSO transdermal system?

The SANCUSO transdermal system comes inside a pouch which is inside the carton.

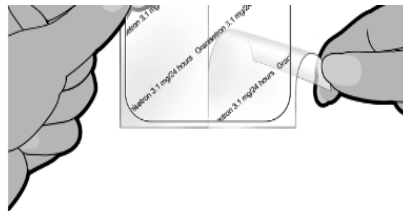
1. Do not remove the SANCUSO transdermal system from the pouch until you are ready to use it.
2. **Do not** cut the SANCUSO transdermal system into pieces.
3. Remove the pouch from the carton.



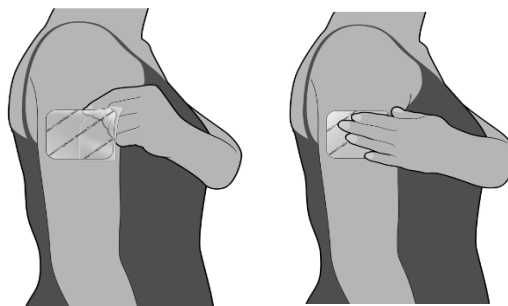
4. Tear the pouch open at the notch provided, and remove the SANCUSO transdermal system. Each pouch contains one SANCUSO transdermal system stuck onto a stiff (rigid) plastic film.



5. The unprinted, sticky side of the SANCUSO transdermal system is covered by a 2-piece stiff (rigid) plastic film. Bend the transdermal system in the middle. Slowly peel 1-half of the stiff (rigid) plastic film. Be careful not to stick the SANCUSO transdermal system to itself. Do not touch the sticky side of the SANCUSO transdermal system.



6. While holding the other half of the stiff (rigid) plastic film, apply the sticky half of the SANCUSO transdermal system to your skin. Remove the second half of the stiff (rigid) plastic film and press the whole SANCUSO transdermal system firmly in place and smooth it down with your fingers. Press firmly making sure the SANCUSO transdermal system sticks well to the skin, especially around the edges.



7. Wash your hands with soap and water right away after applying the SANCUSO transdermal system to remove any medicine that may have stuck to your fingers.
8. Keep the SANCUSO transdermal system in place for the whole time you are receiving your chemotherapy treatment. Remove the SANCUSO transdermal system at least 1 day (24 hours) after your chemotherapy treatment is finished. The SANCUSO transdermal system can be worn for up to 7 days, depending on the number of days your chemotherapy treatment lasts.

9. **Do not** re-use the SANCUSO transdermal system after you remove it. See the instructions below on the right way to remove and throw away the SANCUSO transdermal system.

What do I do if the SANCUSO transdermal system does not stick well?

If the SANCUSO transdermal system does not stick well or the edges lift off the skin, you may apply pieces of surgical or medical adhesive tape on each lifted edge to keep the SANCUSO transdermal system in place. Only place pieces of the surgical or medical adhesive tape on the edges of the SANCUSO transdermal system. Do not completely cover the SANCUSO transdermal system with surgical or medical adhesive tape and do not wrap completely around your arm. If the SANCUSO transdermal system comes more than half off or it becomes damaged (e.g. rips), contact your healthcare provider.

Can I bathe or shower while wearing the SANCUSO transdermal system?

You can continue to shower and wash normally while wearing the SANCUSO transdermal system.

It is not known how other activities, for example swimming, strenuous exercise or using a sauna or whirlpool, may affect the SANCUSO transdermal system. **Avoid these activities while wearing the SANCUSO transdermal system.**

How do I remove and dispose of the SANCUSO transdermal system?

1. When you remove the SANCUSO transdermal system, peel it off gently.
2. The used SANCUSO transdermal system will still contain some of the medicine. After removing the used SANCUSO transdermal system, fold it in half so that the sticky side sticks to itself. Throw away the used SANCUSO transdermal system in the trash right away so that children and pets cannot reach it.
3. If any adhesive (glue) remains on your skin after you remove the SANCUSO transdermal system, wash the area with soap and water to remove it. Do not use alcohol or other dissolving liquids, such as nail polish remover. These may cause skin irritation.
4. Wash your hands with soap and water after handling the SANCUSO transdermal system.
5. You may see mild redness on the skin where the SANCUSO transdermal system is removed. This redness should go away within 3 days. If redness continues, tell your healthcare provider.

What are the ingredients in the SANCUSO transdermal system?

Active ingredient: granisetron.

Inactive ingredients: acrylate-vinylacetate copolymer, polyester, titanium dioxide, polyamide resin and polyethylene wax.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured by:

Kindeva Drug Delivery L.P.
Northridge, CA 91324

Manufactured for:

Cumberland Pharmaceuticals Inc., Nashville, TN 37203

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