

Patient Information

Sancuso® [san-KOO-so] (granisetron transdermal system)

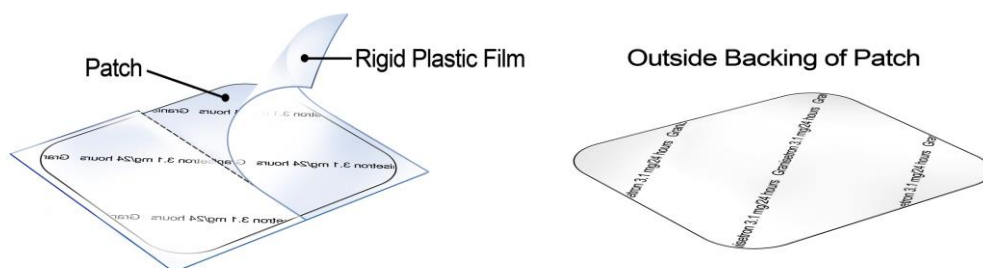
IMPORTANT: For skin use only

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 people receiving some types of chemotherapy treatment. Sancuso is a skin patch that slowly releases the medicine contained in the adhesive (glue), through clean and intact skin areas into your bloodstream while you wear the patch.

Important: Sancuso contains granisetron, the same medicine in Kytril. Do not take Kytril at the same time you use Sancuso unless your healthcare provider tells you it is alright.



Who should not use Sancuso?

Do not use Sancuso if you are allergic to 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?

Tell your healthcare provider about all your medical conditions, including if you:

- are allergic to medical adhesive tape, adhesive dressings or other skin patches
- 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 breast-feeding or plan to breast-feed. It is not known if Sancuso passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Other medicines may affect how Sancuso works. Sancuso may also affect how other medicines work.

How should Sancuso be used?

Use Sancuso exactly as prescribed. See the detailed Patient Instructions for Applying Sancuso at the end of this Patient Information leaflet.

What should I avoid while using Sancuso?

Do not apply any heat source over or near the Sancuso patch. For example,

- A heating pad or heat lamp should not be used where the patch is applied.
- You should avoid extended exposure to heat as it may increase your blood levels during the time of heat exposure.

Avoid sunlight. The medicine in Sancuso (granisetron) may not work as well and/or may affect your skin if exposed to direct sunlight or the light from sunlamps or tanning beds. It is important to do the following:

- While you wear the patch, keep it covered with clothing if you will be in sunlight or near a sunlamp, including tanning beds.
- Keep the skin where Sancuso was applied covered for another 10 days after the patch is taken off to protect from exposure to direct sunlight.

What are the possible side effects of Sancuso?

Sancuso can cause serious side effects:

- **Using Sancuso may make it harder to identify certain stomach and bowel problems that are from other causes.** Tell your healthcare provider if you have any stomach area (abdominal) pain or swelling while using Sancuso.
- **Skin reactions.** Skin reactions can happen just at the patch application site or outside the patch application site. Tell your healthcare provider if you get any redness, rashes, bumps, blisters or itching at the patch application site, and especially if they spread outside the place where the patch was or if they appear outside the patch application site. You may need to stop using Sancuso.

Common side effects of Sancuso are:

- constipation
- headache.

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?

- Keep Sancuso in the package it comes in.
- Store Sancuso at 20-25°C (68-77°F).

Keep Sancuso out of the reach of children.

General information about Sancuso

Medicines are sometimes prescribed for conditions that are not mentioned in Patient Information leaflets. Do not use Sancuso for a condition for which it is not prescribed. Do not give Sancuso to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about Sancuso. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about Sancuso that is written for health professionals.

For more information, go to www.sancuso.com or call 1-800-SANCUSO.

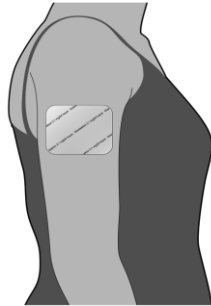
Patient Instructions for Applying Sancuso

When do I apply the Sancuso patch?

- Apply Sancuso at least 1 day (24 hours) before your scheduled chemotherapy treatment.
- You may apply Sancuso up to 2 days (48 hours) before your scheduled chemotherapy.
- Wear the patch all the time during your chemotherapy.
- Sancuso may be worn for up to 7 days, depending on how long your chemotherapy treatment lasts (up to 5 days).
- Remove the patch at least 1 day (24 hours) after your chemotherapy is finished.
- Keep the patch covered, such as under clothing, while you are wearing it to avoid a skin reaction to sunlight or sunlamps. Keep the skin where Sancuso was applied (application site) covered up for another 10 days after the patch is taken off to prevent a skin reaction. See “What should I avoid while using Sancuso?”

Where do I apply the Sancuso patch?

- Apply Sancuso to a clean, dry, healthy area of skin on the outside part of your upper arm.

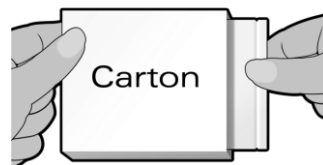


- The area you choose should not be oily, recently shaved or have any skin problems such as being damaged (cut or scraped) or irritated (redness or a rash).
- **Do not apply Sancuso to areas that have been treated with creams, oils, lotions, powders or other skin products that could keep the patch from sticking well to your skin.**

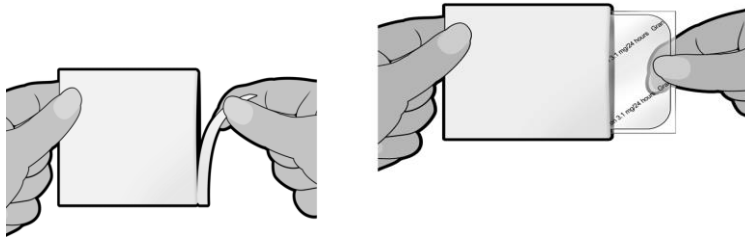
How do I apply the Sancuso patch?

The Sancuso patch comes inside a pouch which is inside the carton.

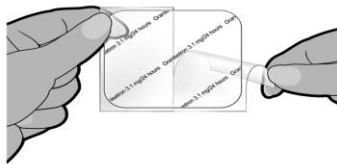
1. Do not remove the patch from the pouch until you are ready to use it.
2. **Do not cut the Sancuso patch into pieces.**
3. Remove the pouch from the carton.



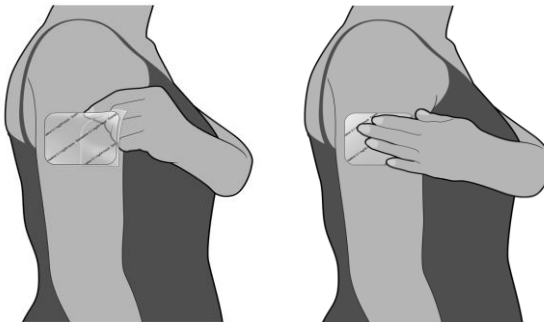
4. Tear the pouch open using the slit provided, and remove the patch. Each pouch contains one Sancuso patch stuck onto a rigid plastic film.



5. The unprinted, sticky side of the patch is covered by a two-piece rigid plastic film. Bend the patch in the middle and remove one half of the rigid plastic film. Be careful not to stick the patch to itself and avoid touching the sticky side of the patch.



6. While holding the remaining half of the rigid plastic film, apply the patch to your skin. Remove the second half of the rigid plastic film and press the whole patch firmly in place with your fingers and smooth down. Press firmly making sure it sticks well to the skin, especially around the edges.



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

9. Do not re-use the patch after you remove it. See below for instructions on the right way to remove and throw away the patch.

What to do if the Sancuso patch does not stick well?

If the patch does not stick well, you may use surgical bandages or medical adhesive tape to keep the patch in place. Place tape or bandages on the edges of the patch. Do not completely cover the patch with bandages or tape and do not wrap completely around your arm. If the patch comes more than half off or it becomes damaged see your healthcare provider.

Can I bathe or shower while wearing Sancuso?

You can continue to shower and wash normally while wearing the Sancuso patch. It is not known how other activities, for example swimming, strenuous exercise or using a sauna or whirlpool, may affect Sancuso. Avoid these activities while wearing Sancuso.

How do I remove and dispose of Sancuso?

1. When you remove the patch, peel it off gently.
2. The used patch will still contain some of the medicine. After removing the used Sancuso patch, fold it in half so that the sticky side sticks to itself. Throw away the Sancuso patch in the garbage, out of the reach of children and pets. Do not re-use the patch.
3. After removing the patch you may find some adhesive is left on your skin. Gently 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 after handling the patch.
5. You may see mild redness on the skin where the patch is removed. This redness should go away within three days. If redness continues, tell your healthcare provider.

What are the ingredients in Sancuso?

Active ingredient: granisetron.

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

Manufactured by:

3M Drug Delivery Systems, St. Paul, MN 55107

Manufactured for:

Kyowa Kirin, Inc., Bedminster, NJ 07921

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