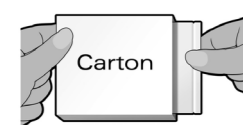


Perf → ← Fold

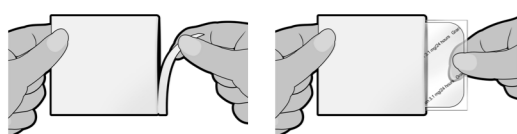
How do I apply the Sancuso patch?

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

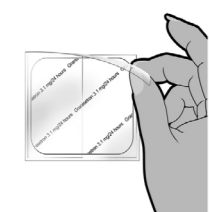
- Do not remove the patch from the pouch until you are ready to use it.
- Do not cut the Sancuso patch into pieces.**
- Remove the pouch from the carton.



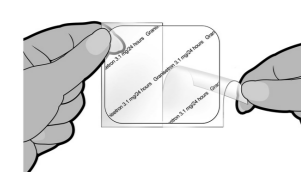
- Tear the pouch open using the slit provided, and remove the patch. Each pouch contains one Sancuso patch stuck onto a rigid plastic film, and a separate thin, clear protective liner.



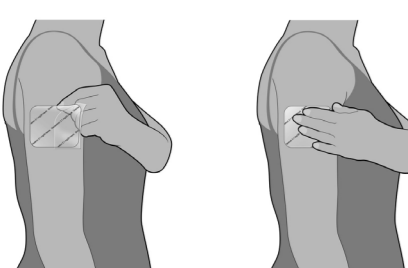
- Remove the thin, clear protective liner to expose the printed side of the patch. Throw away the liner. The protective liner is only included in the pouch to separate the patch from the inside of the pouch, and is not part of the patch.



- 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.



- 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.



- Wash your hands right away after applying the patch to remove any medicine that may have stuck to your fingers.
- 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.
- 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?

- When you remove the patch, peel it off gently.
- 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.
- 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.
- Wash your hands after handling the patch.
- 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:

Aveva Drug Delivery Systems Inc., Miramar, FL 33025

Manufactured for:

ProStrakan Inc., Bedminster, NJ 07921

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Revised: September 2011

13 NONCLINICAL TOXICOLOGY**13.1 Carcinogenesis, Mutagenesis and Impairment of Fertility**

In a 24-month carcinogenicity study, rats were treated orally with granisetron 1, 5 or 50 mg/kg/day (6, 30 or 300 mg/m²/day). The 50 mg/kg/day dose was reduced to 25 mg/kg/day (150 mg/m²/day) during week 59 due to toxicity. For a 50 kg person of average height (1.46 m² body surface area), these doses represent about 2.6, 13 and 65 times the recommended clinical dose (3.1 mg/day, 2.3 mg/m²/day, delivered by the Sancuso patch, on a body surface area basis). There was a statistically significant increase in the incidence of hepatocellular carcinomas and adenomas in males treated with 5 mg/kg/day (30 mg/m²/day, about 13 times the recommended human dose with Sancuso, on a body surface area basis) and above, and in females treated with 25 mg/kg/day (150 mg/m²/day, about 65 times the recommended human dose with Sancuso, on a body surface area basis). No increase in liver tumors was observed at a dose of 1 mg/kg/day (6 mg/m²/day, about 2.6 times the recommended human dose with Sancuso, on a body surface area basis) in males and 5 mg/kg/day (30 mg/m²/day, about 13 times the recommended human dose with Sancuso, on a body surface area basis) in females.

In a 12-month oral toxicity study, treatment with granisetron 100 mg/kg/day (600 mg/m²/day, about 261 times the recommended human dose with Sancuso, on a body surface area basis) produced hepatocellular adenomas in male and female rats while no such tumors were found in the control rats. A 24-month mouse carcinogenicity study of granisetron did not show a statistically significant increase in tumor incidence, but the study was not conclusive.

Because of the tumor findings in rat studies, Sancuso should be prescribed only at the dose and for the indication recommended (see INDICATIONS AND USAGE, and DOSAGE AND ADMINISTRATION).

Granisetron was not mutagenic in an *in vitro* Ames test and mouse lymphoma cell forward mutation assay, and *in vivo* mouse micronucleus test and *in vitro* and *ex vivo* rat hepatocyte UDS assays. It, however, produced a significant increase in UDS in HeLa cells *in vitro* and a significant increased incidence of cells with polyploidy in an *in vitro* human lymphocyte chromosomal aberration test.

Granisetron at subcutaneous doses up to 6 mg/kg/day (36 mg/m²/day, about 16 times the recommended human dose of Sancuso, on a body surface area basis), and oral doses up to 100 mg/kg/day (600 mg/m²/day, about 261 times the recommended human dose of Sancuso, on a body surface area basis) was found to have no effect on fertility and reproductive performance of male and female rats.

13.2 Phototoxicity

When tested for potential photogenotoxicity *in vitro* in a Chinese hamster ovary (CHO) cell line, at 200 and 300 mcg/ml, granisetron increased the percentage of cells with chromosomal aberration following photoirradiation.

Granisetron was not phototoxic when tested *in vitro* in a mouse fibroblast cell line. When tested *in vivo* in guinea-pigs, Sancuso patches did not show any potential for photoirritation or photosensitivity. No phototoxicity studies have been performed in humans.

14 CLINICAL STUDIES

The effectiveness of Sancuso in the prevention of chemotherapy-induced nausea and vomiting (CINV) was evaluated in a Phase 3 randomized, parallel group, double-blind, double-dummy study conducted in the U.S. and abroad. The study compared the efficacy, tolerability and safety of Sancuso with that of 2 mg oral granisetron once daily in the prevention of nausea and vomiting in a total of 641 patients receiving multi-day chemotherapy.

The population randomized into the trial included 48% males and 52% females aged 16 to 86 years receiving moderately (ME) or highly emetogenic (HE) multi-day chemotherapy. Seventy-eight (78%) of patients were White, 12% Asian, 10% Hispanic/Latino and 0% Black.

The granisetron patch was applied 24 to 48 hours before the first dose of chemotherapy, and kept in place for 7 days. Oral granisetron was administered daily for the duration of the chemotherapy regimen, one hour before each dose of chemotherapy. Efficacy was assessed from the first administration until 24 hours after the start of the last day's administration of the chemotherapy regimen.

The primary endpoint of the trial was the proportion of patients achieving no vomiting and/or retching, no more than mild nausea and no rescue medication from the first administration until 24 hours after the start of the last day's administration of multi-day chemotherapy. Using this definition, the effect of Sancuso was established in 60.2% of patients in the Sancuso arm and 64.8% of patients receiving oral granisetron (difference -4.89%; 95% confidence interval -12.91% to +3.13%).

An assessment of patch adhesion in 621 patients receiving either active or placebo patches showed that less than 1% of patches became detached over the course of the 7 day period of patch application.

16 HOW SUPPLIED/STORAGE AND HANDLING

Sancuso (Granisetron Transdermal System) is supplied as a 52 cm² patch containing 34.3 mg of granisetron. Each patch is printed on one side with the words "Granisetron 3.1 mg/24 hours". Each patch is packaged in a separate sealed foil-lined plastic pouch.

Sancuso is available in packages of 1 (NDC 42747-726-01) patch.

Store at 20°-25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F). [see USP Controlled Room Temperature].

Sancuso should be stored in the original packaging.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (17.4)

17.1 Gastrointestinal

Because the use of granisetron may mask a progressive ileus and/or gastric distention caused by the underlying condition, patients should be instructed to tell their physician if they have pain or swelling in their abdomen.

17.2 Skin Reactions

Patients should be instructed to remove the patch if they have a severe skin reaction, or a generalized skin reaction (e.g. allergic rash, including erythematous, macular, papular rash or pruritus).

When patients remove the patch, they should be instructed to peel it off gently.

17.3 Exposure to Sunlight

Granisetron may be degraded by direct sunlight or exposure to sunlamps. In addition, an *in vitro* study using Chinese hamster ovary cells suggests that granisetron has the potential for photogenotoxicity (see Section 13.2).

Patients must be advised to cover the patch application site, e.g. with clothing, if there is a risk of exposure to sunlight or sunlamps throughout the period of wear and for 10 days following its removal.

Rx Only**Manufactured by:**

Aveva Drug Delivery Systems Inc.,
Miramar, FL 33025

**Manufactured for:**

ProStrakan Inc.,
Bedminster, NJ 07921



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Rev. 09/11

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17.4 FDA-Approved Patient Labeling**Patient Information**

Sancuso® [san-KOO-so] (Granisetron Transdermal System)

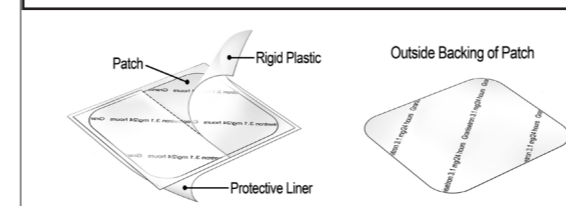
IMPORTANT: For skin use only

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?

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.

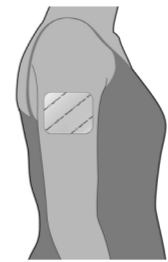
For more information, go to www.sancuso.com or call 1-800-SANCUSO.

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.**

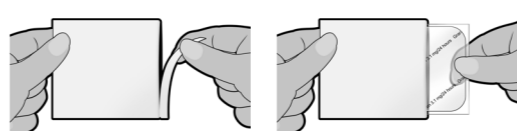
How do I apply the Sancuso patch?

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

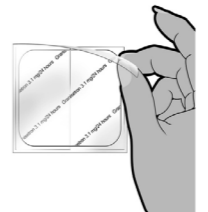
- Do not remove the patch from the pouch until you are ready to use it.
- Do not cut the Sancuso patch into pieces.**
- Remove the pouch from the carton.



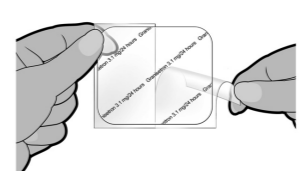
- Tear the pouch open using the slit provided, and remove the patch. Each pouch contains one Sancuso patch stuck onto a rigid plastic film, and a separate thin, clear protective liner.



- Remove the thin, clear protective liner to expose the printed side of the patch. Throw away the liner. The protective liner is only included in the pouch to separate the patch from the inside of the pouch, and is not part of the patch.



- 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.



- 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.



- Wash your hands right away after applying the patch to remove any medicine that may have stuck to your fingers.

- 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.

- 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?

- When you remove the patch, peel it off gently.
- 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.

- 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.
- Wash your hands after handling the patch.
- 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.

ProStrakan Limited Galabank Business Park, Galashiels, UK, TD1 1QH Tel: +44 (0) 1896 664 000 Fax: +44 (0) 1896 664 001		ProStrakan		Product No:	PG2193	Colours Used	
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				Item Description:	Patient Information Leaflet		
				Cutter Ref:			
				Pharmacode			
				Manufacturer Code:			
				Actual Size:	39.375" x 13.375"		
				Market:	US		
				Language:	English		
				Proof No:	4		
				Date Issued:	22-Dec-11		
				Issues by:	Vanessa Turner		

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