When to Consider SANCUSO® (Granisetron Transdermal System)

Due to its route of administration, SANCUSO® may be an alternate option for patients who are unable to take or retain daily oral antiemetics 1,2,3

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*SANCUSO is not indicated for radiation-induced nausea and vomiting.

**Chemolysis** refers to the removal of substances using chemical agents.

**Difficulty Swallowing** and **Limited Motility/Absorption** are potential complications associated with chemotherapy regimens.

**Important Information**

SANCUSO is contraindicated in patients with known hypersensitivity to granisetron or to any of the components of the patch. Granisetron may mask a progressive ileus and/or obstruction.

**Possible Causes:**

- Side effects from chemotherapy with/without radiation, such as: (severe)
  - mouth sores
  - oral mucositis
  - oral infections
  - dysphagia

- Tumor-related dysmotility

- Chemotherapy

- Oral mucositis

- Radiation-induced small bowel disease

- Bowel obstructions or perforations

- Possible complications include oral mucositis, nausea, vomiting, constipation, and bowel obstruction.

**Important Information:**

SANCUSO is associated with a syndrome that has been reported with 5-HT3 receptor antagonists. If symptoms of serotonin syndrome occur, discontinue SANCUSO and initiate supportive treatment.

**Possible symptoms:**

- Increased body temperature
- Increased heart rate
- Diaphoresis
- Muscular rigidity
- Miosis
- Prolonged QT interval

**Important Information:**

If you check any of the boxes below, consider SANCUSO for your patient. Because it’s a patch, SANCUSO may be appropriate for mechanically compromised patients for whom daily oral antiemetics may not be an option.

- Side effects from chemotherapy with/without radiation, such as:
  - mouth sores
  - Oral mucositis
  - Oral infections
  - Dysphagia

- Tumor-related dysmotility

- Chemotherapy

- Oral mucositis

- Radiation-induced small bowel disease

- Bowel obstructions or perforations

**Possible cautions:**

- Patients should avoid direct exposure of application site to natural or artificial sunlight by covering with clothing while wearing the patch and for 10 days after removing it. The use of sunscreen with the patch may cause skin irritation at the application site.

- Patients should not be exposed to heat sources such as electric blankets, heating pads, or sun lamps. When handling the patch, the patient should follow the instructions for use to prevent skin irritation.

- Patients should not use the patch if they have any known drug allergy or if they are pregnant or nursing.

**References:**

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### Key Points

#### Difficulty Swallowing
- Side effects from chemotherapy without radiation, such as:
  - Nausea
  - Vomiting
  - Pain
  - Fatigue
  - Dizziness

#### Limited Gut Motility/Absorption
- Tumor-related dyssmotility
- Chemoradiation

#### Possible causes:
- Side effects from chemotherapy without radiation, such as:
  - Nausea
  - Vomiting
  - Pain
  - Dizziness

#### Important Safety Information
- SANCUSO is contraindicated in patients with known hypersensitivity to granisetron or to any of the components of the patch. Granisetron may mask a progressive illness and gastrointestinal obstruction caused by the underlying condition. Risk of application-site reactions occurring at the site of the patch has been reported. For patients with a history of application-site reactions, alternative antiemetic treatment should be considered.

#### References

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#### CANCER TYPE
- Head and neck
- Breast
- Lung
- Gastrointestinal
- Gynecological
- Testicular
- Colorectal

#### TREATMENT REGIMENS
- Chemotherapy
- Patient-based (capillar, radiation)
- Microtubule (e.g. oral mucositis)
- Antimetabolite
- Anthracycline (e.g. oral mucositis)
- Alkylating agent

#### POSSIBLE COMPLICATIONS
- Difficulty swallowing
- Limited Gut Motility/Absorption
- Opioids taken for pain management

#### Indication
- SANCUSO (Granisetron Transdermal System) is indicated for the prevention of nausea and vomiting in patients receiving chemotherapy for the treatment of non-small cell lung cancer.

Please see additional Important Safety Information on back and full Prescribing Information in pocket.

To learn more about SANCUSO, call 1-800-726-2376 or visit www.SANCUSO.com.
INDICATIONS AND USAGE

Sancuso is indicated for the prevention of chemotherapy-induced nausea and vomiting associated with highly emetogenic chemotherapy (HEC) and moderately emetogenic chemotherapy (MEC) treatments, and is used in combination with other antiemetics.

DOSAGE FORMS AND STRENGTHS

Sancuso is available as a skin patch containing 3.1 mg of granisetron hydrochloride, which is slowly released over 24 hours.

CONTRAINDICATIONS

Sancuso is contraindicated in patients with a history of hypersensitivity to granisetron or any other components of the product.

WARNINGS

Serotonin Syndrome

The risk of serotonin syndrome is increased when Sancuso is used concomitantly with other 5-HT3 receptor antagonists, as well as with serotonergic drugs such as selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs), tryptophan, selective serotonin uptake inhibitors (SSUs), and St. John's wort.

Gastrointestinal Effects

Serotonin syndrome may affect the gastrointestinal system, leading to symptoms such as nausea, vomiting, diarrhea, constipation, abdominal pain, and ileus.

Hepatic and Renal Impairment

Sancuso is not recommended for use in patients with moderate or severe hepatic or renal impairment.

Pregnancy

Sancuso should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

Sancuso is released into breast milk, and there have been reports of serotonin syndrome in infants of women treated with Sancuso.

Management of Overdose

Overdose with Sancuso is not expected to result in severe toxicity. However, if overdose occurs, supportive management may include monitoring for symptoms of serotonin syndrome and gastrointestinal effects.

PHARMACOKINETICS

Granisetron is rapidly absorbed following transdermal administration, with peak plasma concentrations occurring within 48 to 72 hours. The elimination half-life is approximately 2 hours.

INTERACTIONS

Drug Interactions

Sancuso should not be used concomitantly with drugs that can increase the risk of serotonin syndrome. This includes strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, voriconazole,Saquinavir, and ritonavir), moderate CYP3A4 inhibitors (e.g., diltiazem, verapamil, and erythromycin), and strong CYP3A4 inducers (e.g., St. John's wort).

SEROTONIN SYNDROME

Serotonin syndrome (including altered mental status, hyperpyrexia, myoclonus, shivering, fasciculation, tremor, diaphoresis, autonomic instability, and coma) may occur in patients taking Sancuso concomitantly with 5-HT3 receptor antagonists, SSRIs, SNRIs, MAOIs, or tryptophan supplements.

CLINICAL PHARMACOLOGY

Pharmacological Activity

Granisetron is a potent, selective 5-HT3 receptor antagonist, which prevents the release of acetylcholine from the enteric neurons of the gut, thereby suppressing nausea and vomiting.

Pharmacokinetics

Granisetron hydrochloride is absorbed slowly following transdermal administration, with peak plasma concentrations occurring within 48 to 72 hours. The elimination half-life is approximately 2 hours.

CLINICAL STUDIES

The efficacy of Sancuso was evaluated in clinical trials involving patients with chemotherapy-induced nausea and vomiting.

CONTRAINDICATIONS

Sancuso is contraindicated in patients with a history of drug-induced hypersensitivity to granisetron or any component of the product.

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How should Sancuso be used?

How do I apply the Sancuso patch?

1. Choose a location to apply the Sancuso patch. The location will usually be on the abdomen, upper chest, back, or upper arm. The location must be clean and dry. The skin should not be irritated (redness or a rash).

2. Remove the pouch from the carton.

3. Remove the thin, clear protective liner to expose the printed side protective liner.

4. Wash your hands after handling the patch.

5. You may see mild redness on the skin where the patch is applied. It is not known how other activities, for example swimming, strenuous exercise or using a sauna or whirlpool, suggest that granisetron has the potential for effect on fertility and reproductive performance of rats and mice. Granisetron was not genotoxic when tested in a mouse fibroblast cell line. When tested for potential photogenotoxicity and for the indication recommended in the US, Sancuso patches did not induce chromosomal damage in human lymphocytes. When tested ex vivo and in guinea-pigs, Sancuso patches did not cause any increase in the frequency of micronuclei in bone marrow cells compared with controls. A single 2 mg dose in guinea-pigs increased the percentage of cells with chromosomal damage for about three hours. When Sancuso was administered at a dose of 3.1 mg/24 hours for 14 days, it had no effect on the haematopoietic system. As phototoxicity, the potential for Sancuso to cause skin irritation on exposure to sunlight was assessed both in vitro and in vivo in the animal model. In vitro, Sancuso did not cause skin irritation on exposure to ultraviolet-B light. In vivo, Sancuso did not cause skin irritation when applied to guinea-pig skin at the LEO skin irritation score of 1.5, and for the indication recommended in the USA, Sancuso did not cause any increase in the number of granulocytes in human whole blood cultures compared with controls.

6. While holding the remaining half of the rigid plastic film, apply any medicine that may have stuck to your fingers.

7. While holding the remaining half of the rigid plastic film, apply the patch to the location that was chosen in step 1. Be careful not to touch the adhesive side of the patch. Apply the patch as flat as possible on the skin surface. The patch can be worn for up to 24 hours, depending on how long your chemotherapy is finished. The patch can be worn for up to 24 hours, depending on how long your chemotherapy is finished. The patch can be worn for up to 24 hours, depending on how long your chemotherapy is finished.

8. When removing the patch, follow the instructions on the patch. Do not re-use the patch after you remove it. If the patch does not stick well, you may use it.

9. You can continue to shower and wash normally while using Sancuso. When removing the patch, do not remove it by gripping the edges. You can continue to shower and wash normally while using Sancuso. When removing the patch, do not remove it by gripping the edges.

10. Do not re-use the patch after you remove it.

11. The medicine in Sancuso is an acrylate-vinylacetate copolymer, polyester, titanium dioxide, resin and polyethylene wax. Inactive ingredients: acrylate-vinylacetate copolymer, polyester, titanium dioxide, resin and polyethylene wax.