Indications and Usage

SANCUSO (granisetron transdermal system) is indicated for the prevention of nausea and vomiting in adults receiving moderately and/or highly emetogenic chemotherapy regimens of up to 5 consecutive days.

Important Safety Information

Contraindications

SANCUSO is contraindicated in patients with known hypersensitivity to granisetron or to any of the components of the transdermal system.

Warnings and Precautions

Progressive Ileus and Gastric Distention: SANCUSO may mask a progressive ileus and/or gastric distention. This should be particularly considered before use of SANCUSO in patients who have had recent abdominal surgery. Monitor for decreased bowel activity, particularly in patients with risk factors for gastrointestinal obstruction.

Serotonin Syndrome: The development of serotonin syndrome has been reported with 5-HT3 receptor antagonists. Patients should be monitored for the emergence of serotonin syndrome, especially with concomitant use of SANCUSO and other serotonergic drugs. If symptoms of serotonin syndrome occur, discontinue SANCUSO and initiate supportive treatment. Patients should be informed of the increased risk of serotonin syndrome, especially if SANCUSO is used concomitantly with other serotonergic drugs.

Skin Reactions: In clinical trials with SANCUSO, application site reactions were reported that were generally mild in intensity and did not lead to discontinuation of use. The incidence of reactions was comparable with placebo. If severe reactions, or a generalized skin reaction occur (e.g., allergic rash, including erythematous, macular, papular rash or pruritus), remove the SANCUSO transdermal system.

Increased Drug Exposure with Use of External Heat Sources: Prolonged exposure to heat results in increasing plasma concentrations of granisetron during the period of heat exposure. Do not apply a heat pad or heat lamp over or in the vicinity of the SANCUSO transdermal system and avoid extended exposure to heat.

Phototoxicity with Ultraviolet Light Exposure: Granisetron may be affected by direct natural or artificial sunlight, including sunlamps. An in vitro study using Chinese hamster ovary cells suggests that granisetron has the potential for photogenotoxicity. To avoid a potential skin reaction, advise patients to cover the application site of the transdermal system with clothing if there is a risk of exposure to direct natural or artificial sunlight throughout the period of wear and for 10 days following its removal.

Adverse Reactions

The most common adverse reaction (≥ 5%) is constipation.

You are encouraged to report suspected adverse reactions to Cumberland Pharmaceuticals, Inc. at 1-833-Sancuso or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information.