Sancuso® (granisetron) transdermal patch

Prescribing Information

Please refer to the full Summary of Product Characteristics before prescribing.

Name: Sancuso 3.1 mg/24 hours transdermal patch. **Active Ingredient:** Each transdermal patch contains 34.3 mg of granisetron releasing 3.1 mg of granisetron per 24 hours. **Indication:** Prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral anti-emetic administration is complicated by factors making swallowing difficult. **Dosage and administration:** ***Adults and the elderly;*** Apply a single patch to clean, dry, intact healthy skin on the outer part of the upper arm, 24 to 48 hours before chemotherapy. The patch should not be placed on skin that is red, irritated or damaged. The patch should be removed a minimum of 24 hours after completion of chemotherapy, and can be worn for up to 7 days depending on the duration of the chemotherapy regimen. ***Children and adolescents;*** Must not be used in patients less than 18 years old. ***Renal or hepatic impairment;*** No dose adjustment is necessary; however, a degree of caution must be exercised in this population. **Adverse effects:** The most frequently observed adverse reaction is constipation (common). Uncommon adverse events include decreased appetite, headache, vertigo, flushing, dry mouth, nausea, retching, arthralgia, generalised oedema and application site irritation. Class effects for granisetron include QT prolongation and hypersensitivity reactions, e.g. anaphylaxis. Prescribers should consult the summary of product characteristics for further details of side effects. **Precautions:** The use of granisetron may reduce lower bowel motility. Patients with signs of sub-acute intestinal obstruction should be monitored closely. If a severe application site reaction, or generalized skin reaction occurs the patch must be removed. Granisetron, may be associated with arrhythmias or ECG abnormalities. Patients must be advised to cover the transdermal patch application site, e.g. with clothing, if there is a risk of exposure to sunlight while wearing the patch, and for 10 days following its removal and to avoid activities such as swimming, strenuous exercise or using a sauna or whirlpool while wearing SANCUSO. Showering or washing normally can be continued. External heat (for example hot water bottles or heat pads) should be avoided on the area of the patch. There have been reports of serotonin syndrome with 5-HT3 antagonists, usually in combination with other serotonergic drugs including Selective Serotonin Reuptake Inhibitors or Serotonin Norepinephrine Reuptake Inhibitors. Appropriate observation of patients for serotonin syndrome-like symptoms is advised. **Pregnancy and lactation:** Avoid using Sancuso during pregnancy and lactation. **Contraindications:** Hypersensitivity to granisetron and other 5-HT3 receptor antagonists or to any of the components of the patch. **Legal classification:** POM. **Marketing Authorisation Number:** For Great Britain: PLGB 50262/0009. For Northern Ireland and the Republic of Ireland: EU/1/12/766/001. **Marketing Authorisation Holder:** Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132NP Hoofddorp, The Netherlands. **Date of prescribing information:** 1st December 2023.

For Great Britain and Northern Ireland:

NHS cost: 1 transdermal patch per carton; £56.

Adverse Events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse Events should also be reported to Kyowa Kirin International UK NewCo Ltd, known as Grünenthal Meds on Tel: +44 (0)1896 664000, email: PVUK@grunenthalmeds.com

For the Republic of Ireland:

Adverse Events should be reported. Information about adverse event reporting can be found at www.hpra.ie. Adverse Events should also be reported to Kyowa Kirin International NewCo IE Ltd, known as Grünenthal Meds on Tel: +44 (0)1896 664000, email: PVUK@grunenthalmeds.com