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EPAR summary for the public

Sancuso

granisetron

This is a summary of the European public assessment report (EPAR) for Sancuso. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Sancuso.

What is Sancuso?

Sancuso is a medicine that contains the active substance granisetron. It is available as a transdermal patch (a patch that delivers a medicine across the skin). Each patch releases 3.1 mg of granisetron over 24 hours.

Sancuso is a 'hybrid generic medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but given in a different way. While the reference medicine for Sancuso is Kytril taken by mouth, Sancuso is a patch applied to the skin.

What is Sancuso used for?

Sancuso is an 'anti-emetic', a medicine that prevents nausea (feeling sick) and vomiting. It is used to prevent nausea and vomiting caused by types of chemotherapy (medicines used to treat cancer) that are moderate or strong triggers of nausea and vomiting. Sancuso is only used in adults who would have difficulty swallowing medicines and when the chemotherapy lasts from three to five days.

The medicine can only be obtained with a prescription.

How is Sancuso used?

One transdermal patch is applied 24 to 48 hours before chemotherapy. The patch is applied to dry, clean, healthy skin on the outer part of the upper arm or if this is not possible, it may be applied to the abdomen. The patch can remain on the skin for up to seven days depending on the duration of the

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chemotherapy, and it is removed a minimum of 24 hours after completing chemotherapy. The transdermal patch should not be cut into pieces.

How does Sancuso work?

The active substance in Sancuso, granisetron, is a '$5HT_3$ antagonist'. This means that it stops a chemical in the body called 5-hydroxytryptamine (5HT, also known as serotonin) from attaching to $5HT_3$ receptors in the gut. When 5HT attaches to these receptors, it normally causes nausea and vomiting. By blocking these receptors, Sancuso prevents the nausea and vomiting that often happen after certain types of chemotherapy.

How has Sancuso been studied?

Because Sancuso is a hybrid generic, the applicant presented comparative data on the reference medicine in addition to results from its own studies.

The benefit of Sancuso in the prevention of nausea and vomiting caused by chemotherapy was investigated in one main study involving a total of 641 patients. These patients were receiving chemotherapy which was a moderate or strong trigger of nausea and vomiting, lasting for several days. The study compared one Sancuso transdermal patch worn over seven days with granisetron taken by mouth once a day for the duration of the chemotherapy.

The main measure of effectiveness was the number of patients who had their nausea and vomiting under control. This was defined as having no vomiting or retching (strong involuntary contractions of the stomach with the urge to vomit), no more than mild nausea and no need to take other anti-emetic medicines for quick relief after receiving chemotherapy.

What benefit has Sancuso shown during the studies?

Sancuso transdermal patch showed similar effects to granisetron given by mouth in the prevention of vomiting and nausea after chemotherapy: 60.2% of patients receiving the Sancuso transdermal patch (171 out of 284 patients) had their nausea and vomiting under control, compared with 64.8% of patients taking granisetron by mouth (193 out of 298 patients).

What is the risk associated with Sancuso?

The most common side effect with Sancuso (seen in between 1 and 10 patients in 100) is constipation. The majority of adverse reactions were mild or moderate in severity. For the full list of all side effects reported with Sancuso, see the package leaflet.

Sancuso must not be used in people who are hypersensitive (allergic) to granisetron, other $5HT_3$ antagonists or any of the other ingredients.

Why has Sancuso been approved?

The Committee considered that Sancuso transdermal patch showed a similar benefit to granisetron taken by mouth but that it may have a slower onset of action. The CHMP considered however that Sancuso would be of benefit for patients with difficulty swallowing, who might otherwise need to be given daily intravenous injections. Therefore, the CHMP decided that Sancuso's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Sancuso

The European Commission granted a marketing authorisation valid throughout the European Union for Sancuso on 20 April 2012.

The full EPAR for Sancuso can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Sancuso, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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