16 February 2012
EMA/CHMP/56995/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sancuso

granisetron

On 16 February 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sancuso 3.1 mg/24 h transdermal patch intended for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy. The applicant for this medicinal product is ProStrakan Limited. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Sancuso is granisetron, an antiemetic and antinauseant serotonin antagonist (ATC Code: A04AA02). Granisetron is a highly selective antagonist of 5-hydroxytryptamine (5HT3 receptors). Pharmacological studies have demonstrated that granisetron is effective against nausea and vomiting as a result of cytostatic therapy. Radioligand binding studies have demonstrated that granisetron has negligible affinity for other receptor types, including 5HT1, 5HT2, 5HT4 and dopamine D2 binding sites.

The benefits with Sancuso as compared to an oral formulation of granisetron are its ability to provide effective doses of granisetron for the course of the chemotherapy with single administration of the patch removing the need for repeated oral doses for patients who have difficulties to swallow. The most common side effects are constipation, headache and nausea; mild irritant and hypersensitivity reactions are possible at the application side. A Pharmacovigilance plan for Sancuso will be implemented as part of the marketing authorisation.

The approved indication is: SANCUSO transdermal patch is indicated in adults for the 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.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Sancuso and therefore recommends the granting of the marketing authorisation.