Summary of risk management plan for Sancuso (granisetron)

This is a summary of the risk management plan (RMP) for Sancuso. The RMP details important risks of Sancuso, how these risks can be minimised, and how more information will be obtained about Sancuso's risks and uncertainties (missing information).

Sancuso's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sancuso should be used.

This summary of the RMP for Sancuso should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Sancuso's RMP.

I. The medicine and what it is used for

Sancuso is authorised 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 (see SmPC for the full indication). It contains granisetron as the active substance and it is given by transdermal patch.

Further information about the evaluation of Sancuso's benefits can be found in Sancuso's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Sancuso, together with measures to minimise such risks and the proposed studies for learning more about Sancuso's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size - the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status - the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities.*

If important information that may affect the safe use of Sancuso is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Sancuso are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Sancuso. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	Use in paediatrics Use in pregnancy

II.B Missing information

Missing information: Use in paediatrics	
Risk minimisation measures	*SmPC sections 4.2, 4.5 and* 5.2 *PL section 2* Pack size: One patch per pack. Legal status: Prescription-only medicine No additional risk minimisation measures

Missing information: Use in pregnancy	
Risk minimisation measures	*SmPC sections 4.6 and 5.3* *PL section 2* Pack size: One patch per pack. Legal status: Prescription-only medicine No additional risk minimisation measures

II.C Post-authorisation development plan

11.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or any other specific obligations for Sancuso.

11.C.2 Other studies in post-authorisation development plan

There are no studies required for Sancuso.