Summary of risk management plan for CAPECITABINE ORION (CAPECITABINE) Orion Corporation

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

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

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

I. The medicine and what it is used for

Capecitabine Orion is authorised for the treatment of colorectal, gastric and breast cancer (see SmPC for the full indication). It contains capecitabine as the active substance and it is given by mouth.

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

Important risks of Capecitabine Orion, together with measures to minimise such risks and the proposed studies for learning more about Capecitabine Orion'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 the case of Capecitabine Orion, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

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*.

II.A List of important risks and missing information

Important risks of Capecitabine Orion are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 capecitabine. 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	Toxicity in patients with dihydropyrimidine dehydrogenase (DPD) deficiency
Important potential risks	--
Missing information	--

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Important identified risk: Toxicity in patients with dihydropyrimidine dehydrogenase (DPD) deficiency	
Risk minimisation measures	Routine risk minimisation measures: *SmPC sections 4.3, 4.4 and 5.2.* *PL sections 2 and 4.* Information regarding risks related to DPD deficiency and recommendation for pre-treatment testing to identify patients with DPD deficiency. Legal status: Prescription-only medicine. Additional risk minimisation measure: Direct Healthcare Professional Communication regarding pre-treatment testing to identify DPD-deficient patients at increased risk of severe toxicity.

II.C Post-authorisation development plan

There are no studies required for Capecitabine Orion