Summary of risk management plan for Clopidogrel Orion 75 mg film-coated tablets (clopidogrel hydrogen sulfate) Orion Corporation

Date: 30.03.2021, Version 2

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

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

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

I. The medicine and what it is used for

Clopidogrel Orion is authorised for prevention of blood clots (thrombi) forming in hardened blood vessels (arteries), a process known as atherothrombosis, which can lead to atherothrombotic events (such as stroke, heart attack, or death) (see SmPC for the full indication). It contains clopidogrel hydrogen sulfate 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 Clopidogrel Orion, together with measures to minimise such risks and the proposed studies for learning more about Clopidogrel 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 addition to these measures, information about adverse reactions is collected continuously and regularly analysed 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 Clopidogrel 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 clopidogrel. 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	• Major bleeding (including ICH[a])
Important potential risks	• None
Missing information	• None

[a]ICH is applicable especially in TIA/MS indication of DAPT for the first 21 days after TIA/MS events, this indication cumulating multiple risks of bleeding particularly in patients ≥75 years of age.
DAPT: Dual Antiplatelet Therapy; ICH: Intracranial Hemorrhage; MS: Multiple Sclerosis; TIA: Transient Ischemic Attack.

II.B Summary of important risks

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

II.C Post-authorisation development plan

There are no studies required for Clopidogrel Orion.