Summary of risk management plan for Aripiprazole Orion 5 mg, 10 mg, 15 mg, 30 mg tablets (Aripiprazole) Orion Corporation Date: 03.04.2019, Version 2.1

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

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

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

I. The medicine and what it is used for

Aripiprazole Orion is authorized for treatment of schizophrenia, manic episodes in Bipolar I Disorder, and recurrence prevention of manic episodes in Bipolar I Disorder (see SmPC for the full indication). It contains aripiprazole 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 Aripiprazole Orion, together with measures to minimise such risks and the proposed studies for learning more about Aripiprazole 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*.

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

II.A List of important risks and missing information

Important risks of Aripiprazole 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 Aripiprazole Orion. 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	• Extrapyramidal symptoms (EPS) including tardive dyskinesia
Important potential risks	• Orthostatic hypotension
Missing information	• Use in pregnancy and lactation

II.B Summary of important risks

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

II.C Post-authorisation development plan

There are no studies required for Aripiprazole Orion.