sRMP for:

<Product name> 300 mg and 400 mg powder and solvent for prolonged-release suspension for injection (Aripiprazole)

Part VI: Summary of the risk management plan

Summary of risk management plan for <Product name> 300 mg and 400 mg powder and solvent for prolonged-release suspension for injection (Aripiprazole)

This is a summary of the risk management plan (RMP) for <Product name> 300 mg and 400 mg powder and solvent for prolonged-release suspension for injection. The RMP details important risks of <Product name>, how these risks can be minimised, and how more information will be obtained about <Product name>'s risks and uncertainties (missing information). <Product name>'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how <Product name> should be used.

Important new concerns or changes to the current ones will be included in updates of <Product name>'s RMP.

I. The medicine and what it is used for

<Product name> is indicated for maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole (see SmPC for the full indication).

It contains aripiprazole as the active substance and it is administrated parenterally.

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

Important risks of <Product name>, together with measures to minimise such risks and the proposed studies for learning more about <Product name> '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 <Product name>'s 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 <Product name>. 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 including tardive dyskinesia
Important potential risks	• Orthostatic hypotension
Missing information	• Use in pregnancy and lactation • Use in Elderly Patients above 65 Years of Age

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

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

There are no studies which are conditions of the marketing authorisation or specific obligation of <Product name> .

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

There are no studies required for <Product name>.