Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for:

- **Risperidon ratiopharm 25 mg, 37.5 mg, 50 mg powder and solvent for prolonged-release suspension for injection**
- **Risperidon Actavis 25 mg, 37.5 mg, 50 mg powder and solvent for prolonged-release suspension for injection**

This is a summary of the risk management plan (RMP) for RISPERIDONE 25 mg, 37.5 mg, 50 mg powder and solvent for prolonged-release suspension for injection (hereinafter referred to as Risperidone). The RMP details important risks of Risperidone 25 mg, 37.5 mg and 50 mg powder and solvent for prolonged-release suspension for injection, how these risks can be minimised, and how more information will be obtained about Risperidone 25 mg, 37.5 mg and 50 mg powder and solvent for prolonged-release suspension for injection risks and uncertainties (missing information).

Risperidone 25 mg, 37.5 mg and 50 mg powder and solvent for prolonged-release suspension for injection summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Risperidone 25 mg, 37.5 mg and 50 mg powder and solvent for prolonged-release suspension for injection should be used.

Important new concerns or changes to the current ones will be included in updates of Risperidone 25 mg, 37.5 mg and 50 mg powder and solvent for prolonged-release suspension for injection RMP.

I. The Medicine and What It is used for

Risperidone 25 mg, 37.5 mg and 50 mg powder and solvent for prolonged-release suspension for injection is authorised for the maintenance treatment of schizophrenia in adult patients currently stabilised with oral antipsychotics (see SmPC for the full indication). It contains Risperidone as the active substance and it is given intramuscularly.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Risperidone 25 mg, 37.5 mg and 50 mg powder and solvent for prolonged-release suspension for injection, together with measures to minimise such risks and the proposed studies for learning more about Risperidone 25 mg, 37.5 mg and 50 mg powder and solvent for prolonged-release suspension for injection 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 Risperidone 25 mg, 37.5 mg and 50 mg powder and solvent for prolonged-release suspension for injection 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 Risperidone 25 mg, 37.5 mg and 50 mg powder and solvent for prolonged-release suspension for injection. 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).

Table 3: List of important risks and missing information

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

The summary of safety concerns is aligned with the list of safety concerns in the originator's (Risperdal Consta® (risperidone), Janssen-Cilag GmbH) RMP v4.2, approved on 17 February 2020, as displayed in RMP summary published on 12 March 2020 on BfArM webpages (https://www.pharmnet-bund.de/static/de/index.html).

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 Risperidone.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Risperidone.