Part V: Risk minimisation measures (including evaluation of the effectiveness of risk minimisation activities)

Risk Minimisation Plan

V.1. Routine Risk Minimisation Measures

Table Part V.1: Description of routine risk minimisation measures by safety concern

Safety concern	Routine risk minimisation activities
Missing information - Exposure during pregnancy	Routine risk communication: SmPC section 4.7 and 4.8 PIL section 2 and 4 Routine risk minimisation activities recommending specific clinical measures to address the risk: None Other routine risk minimisation measures beyond the Product Information: None

V.2. Additional Risk Minimisation Measures

Not applicable.

V.3 Summary of risk minimisation measures

Table Part V.3: Summary table of pharmacovigilance activities and risk minimisation activities by safety concern

Safety concern	Risk minimisation measures	Pharmacovigilance activities
Missing information - Exposure during pregnancy	Routine risk minimisation measures: SmPC sections 4.7 and 4.8 PIL sections 2 and 4 Additional risk minimisation measures: None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: None Additional pharmacovigilance activities: None

Part VI: Summary of the risk management plan

Summary of risk management plan for Paliperidone 25, 50, 75, 100, 150 and 100+150 mg prolonged release suspension for injection in pre-filled syringe (paliperidone)

This is a summary of the RMP for Paliperidone 25, 50, 75, 100, 150 and 100+150 mg prolonged release suspension for injection in pre-filled syringe. The RMP details important risks of Paliperidone, how these risks can be minimised, and how more information will be obtained about Paliperidone's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Paliperidone is indicated for maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, Paliperidone may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed (see SmPC for the full indication). It contains paliperidone as the active substance and it is given by injection.

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

Important risks of Paliperidone 25, 50, 75, 100, 150 and 100+150 mg prolonged release suspension for injection in pre-filled syringe, together with measures to minimise such risks and the proposed studies for learning more about Paliperidone'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.