Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for Paliperidone palmitate 25 mg, 50 mg, 75 mg, 100 mg and 150 mg, Prolonged release suspension for injection in pre-filled syringe

This is a summary of the risk management plan (RMP) for Paliperidone palmitate 25 mg, 50 mg, 75 mg, 100 mg and 150 mg, Prolonged release suspension for injection in pre-filled syringe (hereinafter referred to as Paliperidone). The RMP details important risks of paliperidone, how these risks can be minimized, 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 (PL) give essential information to healthcare professionals (HCPs) 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 palmitate 25 mg, 50 mg, 75 mg, 100 mg and 150 mg, prolonged release suspension for injection in pre-filled syringe is authorized for:

- Paliperidone is indicated for maintenance treatment of schizophrenia in adult patients stabilized with paliperidone or risperidone.
- In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, paliperidone may be used without prior stabilization with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed.

It contains paliperidone palmitate as an active substance and is administered intra-muscularly as prolonged release suspension for injection in pre-filled syringe (25 mg, 50 mg, 75 mg, 100 mg and 150 mg).

II. Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of paliperidone, together with measures to minimize such risks are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and HCPs;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including periodic safety update report assessment (if applicable) 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 paliperidone is not yet available, it is listed under "missing information" below.

II.A List of Important Risks and Missing Information

Important risks of paliperidone are risks that need special risk management activities to further investigate or minimize 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 paliperidone. 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	Exposure during pregnancy

II.B Summary of Important Risks

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

II.C Post-Authorization Development Plan

II.C.1 Studies Which Are Conditions of the Marketing Authorization

There are no studies which are conditions of the marketing authorization or specific obligation of paliperidone palmitate.

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

There are no studies required for paliperidone palmitate.