Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for PALIPERIDONE 25 mg, 50 mg, 75 mg, 100 mg, 150 mg prolonged release suspension for injection

This is a summary of the risk management plan (RMP) for PALIPERIDONE 25 mg, 50 mg, 75 mg, 100 mg, 150 mg prolonged release suspension for injection (hereinafter referred to as Paliperidone). 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 authorised for maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone (see SmPC for the full indication). It contains paliperidone 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 Paliperidone, 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.

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 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 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 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 4: Summary of Safety Concerns

List of important risks and missing information	
Important identified risks	• Cerebrovascular accident
Important potential risks	• Carcinogenicity (pituitary adenomas, endocrine pancreas tumours, breast cancer) • Overall increased mortality in elderly patients with dementia • Cerebrovascular adverse events in elderly patients with dementia • Cognitive and motor impairment • Suicidality • Depression in patients with affective disorders • Increased sensitivity to antipsychotics in patients with Parkinson's disease or dementia with Lewy bodies • Decreased bone mineral density/osteoporosis
Missing information	• Use in haemodialysis patients • Exposure during pregnancy • Exposure via breastfeeding

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 Paliperidone.

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

There are no studies required for Paliperidone.